USER'S MANUAL

EXTREMITER 2010

CONSTRUCTIONAL AND DESIGN MODIFICATION

„BETTER FUTURE“ edition

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1. Intended Use and Basic Description of the Device

The purpose of the device EXTREMITER 2010, „BETTER FUTURE“ edition, is to administer physiotherapeutic vacuum-compression therapy (hereinafter also referred to as VCT), with the aim of favourable influencing organic and functional peripheral capillary return disorders, stagnant metabolism, and impaired trophism in extremities, of vascular, post-traumatic, systemic (primarily diabetic), neurocirculatory, degenerative, and stress aetiology. Application of VCT may also contribute to better circulatory condition of the patient/client.

Fig. 1.1: Example of application of vacuum-compression therapy, administered by the device EXTREMITER 2010, „BETTER FUTURE“ edition, applied on the lower extremity

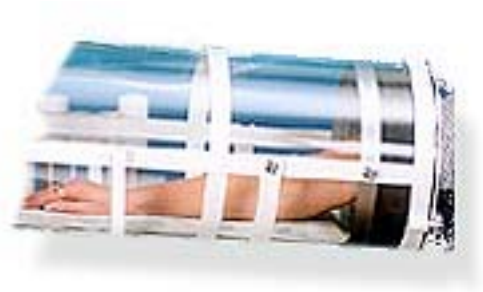


Fig. 1.2: Example of application of vacuum-compression therapy, administered by the device EXTREMITER 2010, „BETTER FUTURE“ edition, applied on the upper extremity

Procedures of vacuum-compression therapy, administered by the device EXTREMITER 2010, „BETTER FUTURE“ edition, are applied mainly in the following branches of medicine:

- Therapeutic rehabilitation and physiotherapy
- Spa sector (balneology)
- Diabetology
- Angiology – vascular medicine
- Phlebology
- Lymphology
- Neurology
- Orthopaedics
- Traumatology – accident medicine
- Surgery (especially vascular surgery)
- Internal medicine
- Preventive and reconditioning medicine
- „Anti-aging“ medicine
- Sports and cosmetic medicine.

Vacuum-compression therapy (VCT) is based on the alternation of negative-pressure and positive-pressure phases in an application cylinder, where the treated extremity is hermetically sealed, and subsequently exposed to a controlled action of hyperbaric (overpressure) and hypobaric (underpressure) environments. Therefore, vacuum-compression therapy is based on the action of alternating hyperbaric and hypobaric environments to a treated lower extremity, or alternatively, to a treated upper extremity.

The extremity to be treated is placed into a transparent plastic application cylinder (1) and hermetically sealed using a rubber inflatable cuff (9), inserted in a cylinder neck (8). The device VAS-07, „BETTER FUTURE“ edition, fully automatically inflates this sealing cuff. The sealing pressure in the cuff is dynamically controlled and minimised, therefore, the treated extremity is not subjected to excessive pressure by the cuff. Technical conditions for the administration of this procedure are fully physiological, and a number of indications of the device are significantly increased (such as phlebologic and lymphologic patients with oedemas of lower extremities, or with algodystrophic syndromes of upper extremities), and, at the same time, operation of this device is significantly simplified. The device´s safety against the undesirable overblowing of the cuff is increasing.

In a positive-pressure phase, the arteriovenous pressure gradient in a capillary bed is strengthened, and blood is expelled centrally through the venous system. This results in improved perfusion and increased absorption of liquids from tissues. At the same time, the volume of venous blood on the periphery, as well as the volume of extravasal fluid, are reduced. By the action of VCT, the fibrinolytic activity is stimulated and thrombotic activity is slightly reduced. If the lymph cycle drainage passageways in the patient's body are free, the lymphatic drainage is accelerated. If the procedure parameters are properly selected, the possible oedema is reduced, the valves are opened. (Fig. 1.3).

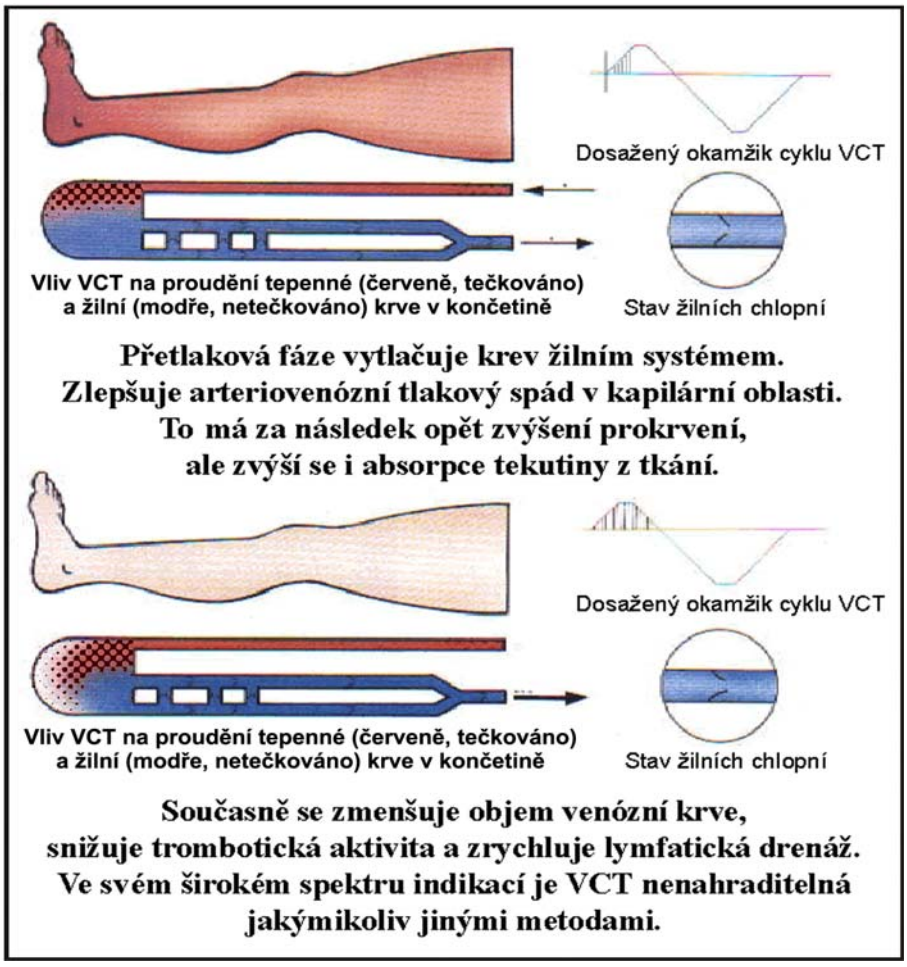

Dosažený okamžik cyklu VCT
Vliv VCT na proudění tepenné (červeně, tečkováno)
a žilní (modře, netečkováno) krve v končetině
Stav žilních chlopní
Přetlaková fáze vytlačuje krev žilním systémem.
Zlepšuje arteriovenózní tlakový spád v kapilární oblasti.
To má za následek opět zvýšení prokrvení,
ale zvýší se i absorpce tekutiny z tkání.
Dosažený okamžik cyklu VCT
Vliv VCT na proudění tepenné (červeně, tečkováno)
a žilní (modře, netečkováno) krve v končetině
Stav žilních chlopní
Současně se zmenšuje objem venózní krve,
snižuje trombotická aktivita a zrychluje lymfatická drenáž.
Ve svém širokém spektru indikací je VCT nenahraditelná
jakýmikoliv jinými metodami.

Fig. 1.3: Schematic representation of vacuum-compression therapy action on the treated extremity in a hyperbaric phase

In a subsequent negative-pressure phase, the extravasal pressure (i.e. pressure in tissues around vessels, outside the vessel volume) is significantly reduced, and the resultant filtration of gases (in particular oxygen), nutrition substances, biocatalyzers, and pharmaceuticals into the tissues in a pressure gradient decline, are increased. The gradual secondary drop of intravasal pressure (pressure inside vessels) is very important, as it stimulates the collateral vascular circulation, and improves perfusion on a long-term basis (Fig. 1.4). Blood is supplied, through opened arterioles and newly created collaterals, also into obliterated peripheral sections where, thanks to an induced pressure gradient, the metabolism between intravasal and extravasal areas is improved. The creation and development of collateral circulation and

neovascularization is stimulated. This results in demonstrably better trophism (nutrition) and metabolism of tissues in the area of treated extremity and even in other near parts of the body.

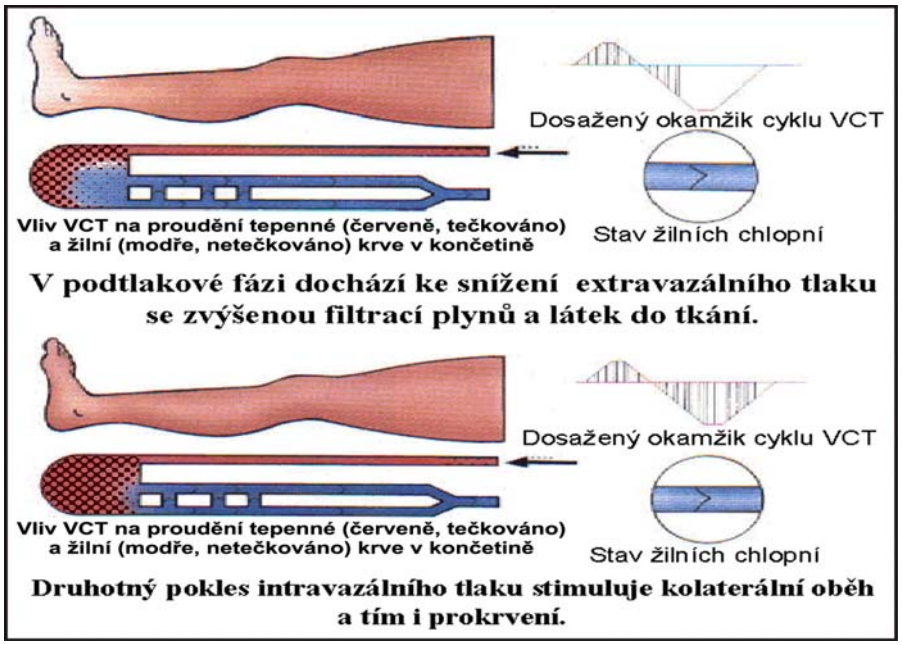

Dosažený okamžik cyklu VCT
Vliv VCT na proudění tepenné (červeně, tečkováno) a žilní (modře, netečkováno) krve v končetině
Stav žilních chlopní
V podtlakové fázi dochází ke snížení extravazálního tlaku se zvýšenou filtrací plynů a látek do tkání.
Dosažený okamžik cyklu VCT
Vliv VCT na proudění tepenné (červeně, tečkováno) a žilní (modře, netečkováno) krve v končetině
Stav žilních chlopní
Druhotný pokles intravazálního tlaku stimuluje kolaterální oběh a tím i prokrvení.

Fig. 1.4: Schematic representation of vacuum-compression therapy action on the treated extremity in a hypobaric stage

Pressure differences, occurring during vacuum-compression therapy, also eliminate the consequences of an increased blood viscosity or reduced elasticity of erythrocytes, and, at the same time, they support nutrition, oxygenation, and exchange of metabolites.

The above-mentioned features of VCT lead to effective, and in other ways hardly achievable possibilities of the physically-therapeutic influence of circulatory disorders in cases of macro-angiopathy, mini-angiopathy, and micro-angiopathy of various aetiology, disorders of capillary return of neurogenic origin, other disorders of peripheral capillary return, trophic disorders, pressure-related disorders in extremities, as well as some types of lymphatic oedemas, post-traumatic states, algodystrophic syndromes, serious systemic diseases (such as diabetes mellitus), stress syndromes, aging related changes, degenerative changes in tissues of extremities, primarily their movement system (such as arthrosis), and their skin cover (for example, trophic defects), and the like. Vacuum-compression therapy may also be utilised for general rehabilitation, reconditioning, preventive, sports and cosmetic purposes. Contraindications are primarily actual and potential thrombosis, suspicion of thrombosis development, risks of bleeding, risks of infection or metastasis dissemination, and serious cases of cardiac insufficiency associated with cardial oedema, or more precisely the edemas of the hepatic origin.

In its therapeutic indications, vacuum-compression cannot be fully substituted with other physiotherapeutic methods, such as devices, which produce only underpressure or only overpressure or even devices which use compressive sleeves for pneumatic drainage. The scope of indication of both these methods is not identical at all:

By their nature, compressive methods of instrument-based lymphatic drainages are based only on the action of pressure when venous blood and lymph are expelled from the extremity, mainly by a gradual local pressure wave in the pressure sleeve, and reduce possible oedema and pressure in peripheral tissues. The circulation is promoted in this passive way, but only if arteries and capillaries are fully capable of utilising such an evoked situation. Instrument-based compressive lymphatic drainages also significantly influence the consistency of oedema from the therapeutical point of view (by changing a solid oedema to elastic one), thus help in creating conditions for the recovery of painless movement of extremity. Compression alone, however, cannot evoke the effective aspiration of a necessary volume of new fresh blood into a partially, or wholly obliterated part of the extremity, and cannot accelerate the circulation process in the periphery and significantly contribute to improvement of metabolism in the affected peripheral tissues also in situations when arteries and capillaries are not able to ensure spontaneously a sufficient supply of blood, or exchange of metabolites, no matter whether this state is a consequence of a disease (diabetes mellitus, angiopathy, trophic

disorders, degenerative disorder of the movement system, ...), or a trauma. As well is not possible to ensure the stimulation of the rise and progress of colaterals.

From a technical point of view, the device EXTREMITER 2010, „BETTER FUTURE“ edition, where the therapeutic application cylinder (1) is made from perfectly transparent cast Plexiglas GR with a technologically ensured elimination of internal stress of materials. This solution ensures high safety of the applicator and its long-term service life without changes in decisive properties, and the ideal possibility to observe visual colour changes in an extremity during the procedure. In particular, it is possible to observe required therapeutic hyperaemia, which occurs in the under-pressure phase and it would reach up to acral parts of the extremity; or to observe changes in a surfaces venous bed. In case trofic defects or chronical consequences of traumas is possible while using the VCT procedure watch the conditionswith the intensity (for example if the defect appears to bleeding). In other ways the extremity with defects will be usually putted into the application cylinder (the defects are properly procure with the sterile protection).

Vertical positioning of the application cylinder (1) and its required tilting is motor-operated and remote-controlled. Putting the application cylinder (1) on the treated extremity in the horizontal direction is performed by two systems:

(a) by feed of the cylinder along the linear guide of a horizontal beam of the application cylinder;
(b) by feed of a vertical supporting arch (2).

According to patient's condition and mutual arrangement of the patient and the device, it is possible to select the option (a) or option (b), or to combine these two options within the sense of their superposition, and to put the application cylinder on the to treated extremity with a limited mobility in a comfortable manner. By the same way the extremity is pushed out from the application cylinder.

Any lateral feed between the treated extremity and application cylinder (1) – i.e. feed at the horizontal level of inserted extremity (if necessary in practical application) is resolved either:

a) by slight lateral movement of the application chair (with the patient) on brake released travelling wheels of the chair and subsequent careful application of wheel brakes in an optimal position, or :
b) by slight lateral movement with the entire device by means of its brake released travelling wheels, and once the optimal position of cylinder against the extremity is achieved, the travelling wheel brakes must be properly applied.

The goal is to achieve such an position of extremity with regard to the cylinder (1), when the extremity is enlaced (surrounded) with the sealing cuff (9) along the periphery uniformly, and the extremity is coaxially (collinearly) positioned with the longitudinal axis of the application cylinder (1) – not sideways. For this reason, the upper extremity (sometimes also the lower extremity) must be padded in the application cylinder (1) using one or several pads. Slightly inflated exercise balls are to be used. The extremity in the cylinder (1) is padded and the extremity will „sink“ into these balls.

All decisive mechanical, electrical and pneumatic parts of the device are well arranged on a robust base of the device, provided with an elegant plastic cover. The powerful control computer, placed in a plastic box (12) at the top of the vertical supporting arch (2), is used for the control of the device and monitoring of administered VCT procedure(s). The device is operated exclusively using a touch screen (13). Procedures from the following five groups (folders) can be selected on this display:

- Well-proven procedures
- Procedures according to diagnoses
- Procedures according to users
- Prescriptions – Procedures, which are prescripted by the doctor on his supervising PC
- Favourite procedures
- Special procedures.

The folder „***Well-Proven Procedures***“ includes physical parameters of the procedures that were successfully used as standard pre-programmed procedures at previous models of the device EXTREMITER 2010. In addition, these procedures are divided into 3 subgroups (subfolders) as follows:

(1) Procedures suitable for the treatment of peripheral arterial circulatory disorders of extremities (arterial disorders),
(2) Procedures suitable for the treatment of conjoint peripheral arterial circulatory disorders of extremities and disorders of venous blood and lymph drainage,
(3) Procedures for the treatment of extremities with oedemas. Especially for venous troubles.

Each subgroup (subfolder) contains 10 pre-programmed procedures, with a gradually increased intensity. The procedure of standard intensity is always sharpened.

The folder „***Procedures According to Diagnoses***" includes approximately 500 therapeutic procedures with very carefully pre-programmed parameters. These therapeutic procedures are divided into 12 basic groups, which are further subsequently hierarchically divided, so, it is very easy and quick to search a particular procedure with necessary parameters for the patient with a particular diagnosis. The basic diagnostic groups for indication of VCT are as follows:

- Peripheral vessel disorders
- Local circulatory disorders of extremities
- Peripheral diabetic complications
- Neurological applications of vacuum-compression therapy
- Musculoskeletal disorders of extremities with an expected therapeutical effect of improved profusion and trophism of tissues
- Vertebrogenous algic syndromes with projections to the upper extremity, or lower extremity
- Oedematous conditions
- Post-traumatic and post-surgery conditions
- Bone disorders of extremities with an expected therapeutical effect of improved profusion and trophism of tissues
- Cosmetic applications
- Elimination of consequences of excessive (or insufficient) stress of extremities, and increase of their physical potential
- Preventive use of vacuum-compression therapy.

Other, more detailed hierarchic structure of these groups is specified in another text of this user's manual.

In the folder „***Procedures According to Users***", the user of the device EXTREMITER 2010, „BETTER FUTURE" edition, may creativity develop procedures with its own parameters.

In the folder „***Favourite Procedures***", favourite and frequently used procedures can be stored, thus facilitate operation of the device.

The folder "***Special Procedures***" is accessible only to researcher workers at this moment. The procedures in this folder are aimed both for various forms of feedback control of vacuum-compression therapy utilizing diagnostic measurements on the patient's extremity being treated in real time, and simultaneous therapeutic utilization of gaseous carbon dioxide.

In the folder ***"Prescription"*** are saved the procedures, which are prescripted by the doctor on his (her) supervising PC, and they are wireless sended to control PC of the device, where they will be applied by the physiotherapeutist.

2 General Information

2.1 Device Manufacturer

EMBITRON s.r.o., Borska 55, 301 00 Plzen, Czech Republic
www.embitron.eu
embitron@embitron.eu

2.2 Authorised Distributor and Service

For the Czech Republic:
EMBITRON s.r.o., Borska 55, 301 00 Plzen, Czech Republic

For other countries: see the list of the authorised distributors and services.

2.3 Purpose of the User's Manual

The purpose of this manual is to provide users of this device and relevant responsible organisations with the necessary information needed for its handling and safe operation. In case of any problems or doubts, the user, or the person responsible, should immediately contact the manufacturer or the authorised distributor.

This manual is intended for all users of this device, as well as responsible organisations that use this medical device in any manner (they: prescribe administration of therapeutic procedures by means of this device, recommend this device to therapeutic, preventive, or reconditioning use, apply therapeutic procedures, operate this device, or supervise the use of this device, and/or are responsible for operation of this device).

This user's manual must be part of each device and available to all persons working/handling with the specified device in any way.

2.4 Guarantees

In accordance with the legal provisions in force, and unless otherwise stipulated in a purchase contract, the guarantee period for the device EXTREMITER 2010, „BETTER FUTURE" edition, is 24 months as from the date of its sale. In the event of warranty claims, the properly completed Guarantee Certificate must be submitted. The guarantee period shall be extended by the time for which the device was repaired in the guarantee time. The guarantee cannot be accepted if the device was not used in accordance with the accompanying documentation (User's Manual) and in accordance with relevant statutory provisions, regulations, and standards. The guarantee shall not be applied to any damage caused by incorrect or improper use of the device, and damage caused by the operator operating this device without proper qualification and/or training in its use. In addition, the guarantee shall not relate to damages caused by fire, water, static electricity, over-voltage, accident, mechanical damage, unprofessional interference with the device, unprofessional installation, discharged or flat accumulators or batteries, as well as consequences of natural wear and tear, and consequence of a force majeure event.

Other conditions for acknowledgement of this guarantee are specific for medical devices:

- A medical device must undergo regular checks of functionality and safety (periodic inspections). These inspections may be performed only and exclusively by the manufacturer or authorised service care provider,
- All service work on the device may be performed only by the manufacturer or authorised service care providers,
- From the viewpoint of legal requirements for complete traceability (vigilance) of medical devices, the manufacturer of the device must know a final user of this device, or relevant responsible organisation,
- The medical device must be properly installed in the user's premises, and operating personnel must be demonstrably trained.

EMBITRON s.r.o is an exclusive authorised provider of service care for this device in the Czech Republic.

The requierement of the producer on the stuff´s qualification:

The prescript of the procedure is performed only by the doctor.
The administration of the procedure is performed only by the medical or by the properly medical trained person.

2.5 Safety Instructions

The device EXTREMITER 2010, „BETTER FUTURE“ edition, was designed and manufactured for as safe as possible use. However, its safe, as well as purposeful and effective use, depends on a qualified prescription of procedure, proper operation, and necessary care and caution. Improper use of this device may result in serious consequences. It is necessary to observe all safety instructions and other information provided for the device EXTREMITER 2010, “BETTER FUTURE“ edition, as well as information in connection with the physical and therapeutic method of vacuum-compression therapy. It is also necessary to follow further development of knowledge in this area of medicine, to apply therapeutic procedures by persons with relevant medical qualification, and to observe all necessary legal provisions, regulations, and recommendations in force.

Users of this device must have available information provided by this user's manual, or other information provided within the framework of training for operating personnel, or in connection with other utilisation of the device EXTREMITER 2010, „BETTER FUTURE“ edition, and applying the physical and therapeutic method of vacuum-compression therapy. In using this device within the framework of health care service provision, a particular procedure must be prescribed by a qualified health care professional, and the operating personnel of this device must also be medically qualified and appropriately trained for operation of this device.

The device must not be used:

- purposes other than the intended purposes of use,
- in an external environment,
- in an environment with the increased risk of electric shock (for example, humid or wet environments, or environments with moving and unsecured mechanical substances),
- in an explosive environment,
- in an environment with the high risk of fire,
- if exposed to adverse weather conditions,
- in inadmissible technical adjustments,
- in noncompliant conditions of electric power supply,
- in absence of a fully responsible user, proper prescription of therapeutic procedure(s), and/or qualified and trained operating personnel,
- in a situation when the patient (client) or his justified interests, or operating personnel and third persons might be threatened by this device, or by the administered therapeutic procedure, or when any other detriment might be caused.

Special warnings:

- When prescribing and applying procedures, it is necessary to respect thoroughly all contraindications, risks, and possible side effects, and always assess individual and actual patient's conditions, as well as other factors.
- The patient's body parts coming to contact with this device must be fully intact or must be treated or covered in such a way that contact with this device or its parts could not cause any risks to the patient or other persons coming to contact with this device.
- The device may be used only in a sufficiently stable position. Falling of any part of the device must be effectively prevented. Any handling with a cylindrical applicator of the device must be performed carefully in order to prevent from injury of the patient. Fixation "Dual" type handles, fixing the cylindrical applicator in its fixing yokes (24) in a selected horizontal position (5), must always be sufficiently tightened. The electromagnetic brake of the supporting arch feed must be applied in the course of procedure administration, see the remote control – OFF position (11bb). The travelling wheels (14) must also be braked.
- It is necessary to check regularly the integrity of all device parts, in particular electric cables, pneumatic air distributions systems, application cylinder, and plastic (laminate) covers (device encapsulation).
- Non-original parts must not be used for this device. No adjustments can be done except adjustments explicitly approved by the manufacturer.
- The device EXTREMITER 2010, „BETTER FUTURE" edition, is a medical device. For that reason, functional checks and safety checks must be performed on a regular basis. These checks are required by relevant statutory provisions (in all EU countries). It is the responsibility of the user and responsible organisation to perform and/or ensure these checks. These functional checks and safety checks may be performed only by the manufacturer of the device, or by the subject authorised by the manufacturer. This subject must be qualified, trained, and equipped with properly calibrated measuring equipment.
- After proper education, the patient (client) may be left under the remote supervision of a qualified medical operator during the procedure only under the condition that his/her health condition and physical and mental capacities enable this. If these conditions are not fulfilled in a reliable way, the patient (client) must be under the permanent supervision of a qualified health care professional during the procedure and shortly after its finishing (if, for example, the risk of a collapse condition or neurovegetative lability exists).
- The device EXTREMITER 2010, „BETTER FUTURE" edition, is a medical device which must not be operated without the supervision of a responsible and qualified health care professional. Such a person must be able to assess and correctly and reliably interpret anamnestic and diagnostic factors leading to an effective, purposeful, and safe application of vacuum-compression therapy. In doing so, this responsible person must also consider all other diagnostic results regarding a particular patient (client), patient's (client's) personality, and all potential risks. It also must take into consideration the viewpoint of preliminary caution, as well as the current knowledge of medical science and research, technical progress, medical legislation, and medical ethics. The patient (client) must be monitored in during the administration of procedure and after its finishing, and, based on the patient's reaction to VAC procedures, an original therapeutic decision must be re-assessed, if necessary (for example, within the meaning of increased number of doses, reduced number of doses, continuation in a series of procedures, repetition of a series of procedures, reduction of the number of procedures, immediate discontinuation of procedure administration, and the like).
- The user of the device EXTREMITER 2010, „BETTER FUTURE" edition, is bound to ensure the device against the risk of fire in a manner that is similar to other electrical appliances supplied from the power supply network. Any abnormal temperature rise of the device (or any of its parts) is a reason to its immediate switch off, disconnection from the power supply network, and subsequent calling a professional repair service without undue delay.
- Ventilation openings or encapsulated parts of the device must not be covered under operation of the device, and the device must not be hermetically closed.
- It is necessary to prevent from ingress of foreign objects and liquids into the device, undesirable vibrations, and sudden temperature changes.
- If a risk of moisture condensation exists (condensation of air water vapours in transfer from colder to warmer areas), the device can be switched on only if it is completely dry.
- Covers of the device may be removed only by the manufacturer, or subject authorised by the manufacturer to perform technical service. Similarly, no other person can disassembly, repair, modify, or otherwise intervene with the device. If this rule is violated, the user of the device will loose the guarantee, and there is also a risk of arbitrary injury and other damages that are not within the manufacturer's responsibility.

- Prior to cleaning or disinfecting the device or any of its parts, the device must be switched off and the detachable mains supply (incoming mains cord) must be disconnected from the power supply by withdrawal of a mains plug from the socket.
- For cleaning and disinfecting, it is necessary to use only safe and well-proven cleaning and disinfecting agents, and, in no case, admit ingress of any liquids into the device or any of its closed (encapsulated) parts.
- CAUTION: Alcohol-based agents must not be used for cleaning or disinfecting of any part of the device. This caution is to be applied, in particular, for the cylinder applicator made of cast Plexiglas. It is not allowed to use any abrasive cleaning agents or tools which would scratch surfaces.
- The device EXTREMITER 2010, „BETTER FUTURE“ edition, similarly as other similar electric instruments, must not be operated in the vicinity of water sources (such as bath-tubs, wash-basin, sinks, swimming pools, laundries, humid basements, and the like).
- The detachable mains supply (incoming mains cord) of the device EXTREMITER 2010, „BETTER FUTURE“ edition, must not be located in areas where the cord could be interrupted or violently pulled out from a socket of electric distribution network or appliance inlet on the real panel of the instrument unit.
- The device EXTREMITER 2010, „BETTER FUTURE“ edition, must be immediately switched off, detachable mains supply (cord) disconnected from the line power supply, and, subsequently, the authorised service should be contacted if any or more of the below-specified cases occur:

- the detachable mains supply (incoming mains cord) is damaged or worn-out,
- the device is exposed to action of water or other liquid, which would leak inside the unit,
- the device does not work normally, changes in performance or behaviour can be seen, non-typical sounds can be heard, or smoke/fume or any odour can be felt,
- the device was damaged by fall or impact,
- the device shows damaged covers, encapsulated parts, control computer, cylinder applicator, and the like, and/or parts responsible for mechanical stability (special care should be taken to integrity and function of the "Dual” type fixation handles),
- any pneumatic distribution systems (hoses), or its connectors, are damaged.

- The use of the device EXTREMITER 2010, „BETTER FUTURE“ edition, must never become a reason for failure to perform, or take away, other necessary medical care procedures.
- The device may be operated only with a fully inserted and secured electrical connectors and couplers, as well as air supply pneumatic connections.
- If it is necessary to adjust the height of the application cylinder in relation to the treated extremity in the course of running procedure, the vertical motor-operated feed along the supporting arch, resp. motor-driven tilting of application cylinder (1), is used. These feeds are remote-controlled.
- In the event of started procedure and inserted extremity in the cylinder (1), these feeds must be performed very gently and with care!

2.6 Technical Characteristics of the Device EXTREMITER 2010, „BETTER FUTURE“ Edition

Health classification	Medical device of Class II a in accordance with the Council Directive 93/42/EEC
Electrotechnical classification	Device supplied from the external power supply source (AC power supply network 230 V / 50 Hz; or 115 V / 60 Hz if so modified by the manufacturer). From the viewpoint of protection against electric shock, the device of Class I
Electrotechnical standard used	CSN EN 60 601 – 1 (eq. IEC 601 – 1)
Classification of applied part of the electrical medical device	BF (according to standard CSN EN 60 601–1, eq. ICE 601-1)
Classification from the viewpoint of protection against ingress of water or solid parts	IP 30 (according to IEC 60 529)
Classification for operation: in areas:	permanent, internal, normal areas without increased risk
Sterilization	This device is not to be sterilized, but ist possible to disinfect it.
Power supply voltage	230 V / 50 Hz, alternating, sinusoidal; or (if so modified by the manufacturer): 115 V / 60 Hz, alternating, sinusoidal
Power required	220 VA
Protection of electrical power supply	2 fuses T 1.25 A, located inside the main switch panel, accessible from outside, and 1 internal fuse used as protection of primary circuit of the network transformer, and 2 fuses T 5A on the DC power supply source board
Pressure produced in the applicator	Therapeutically, max. +/- 15 kPa; compressor – max. +/- 25 kPa
Pressure produced in the cuff	Max. 25 kPa
Control computer	Panel-type computer of PC standard, industrially resistant, with touch screen display DataLab PC/LCD8 1000
Weight of the entire device	Entire device assembly including packaging: 220 kg Entire device assembly without packaging: 150 kg
Dimensions (cm)	Device assembly (packaged): 133(w) x 122(d) x 160(h) Entire device assembly for operation: 120(w) x 110(d) x 120(h) Cylindrical applicator: 100(length) x 32(diameter)
Temperature	Operational: 0 – + 40 C (wtihout sweating) Storage: -10 - +50 C
Atmospheric pressure	Operational: 425 – 809 mmHg Storage: 120 – 809 mmHg
Relative humidity	Operational: 15 – 95% (without sweating) Storage: 5 – 99 %
Material of plastic casing	Laminate and cast Plexiglas GS
Surfaces of metal parts	Stainless, komaxtit and aluminium surface treatment for interiors (sand blast, ground, eloxed)

2.7 Indications and Contraindications of Vacuum-Compression Therapy

2.7.1 Administration of Vacuum-Compression Therapy Procedures

The level of metabolism in peripheral tissues depends on the exchange of gases and resolvable substances between the blood and the tissues in the capillaries. Respectively, it depends on capillary perfusion and capillary filtration. Perfusion corresponds with the amount of open capillaries, and filtration correlates with the transmural pressure, it means intravasal pressure minus extravasal pressure. During a chronic arterial closure, the pressure on periphery is decreased, and filtration is reduced, sometimes followed by consecutive ischemia. At the same time, the compensation development of collateral circulation begins by opening and functional exchange of pre-existing anastomoses. The main stimulus for the creation of a collateral circulation is a decrease in peripheral resistance, along with a decrease in intra-arterial pressure distally from the closure.

Vacuum-compression therapy (VCT) is based on the alternation of negative-pressure and positive-pressure phases (Fig. 2.1, also Fig. 1.3 and 1.4). In the negative-pressure phase, the extravasal pressure is reduced, and filtration of gases and substances into the tissues is increased. The secondary drop of intravasal pressure stimulates the collateral circulation, as well as perfusion. In the positive-pressure phase, the content of blood in the venous system is expelled, and the arteriovenous pressure gradient in the capillary section is improved. This again results in an increase in perfusion and absorption of fluid from tissues. At the same time, the volume of venous blood is reduced, the thrombotic activity is decreased, and lymphatic drainage is accelerated. This fact indicates that the positive-pressure phase should be used for a long time during treatment of chronic venous insufficiency, as well as for some lymphatic oedemas. Of principle for the treatment of circulatory disorders is the controlled vacuum phase, but it is periodically alternated by the effective compression phase.

When setting-up the parameters of the positive-pressure stage, it is necessary to take into consideration the fact that the blood volume (respectively mobilised tissue liquids) displaced from the peripheral tissues may adversely exert the weakened heart of patients with cardiac oedemas. On the contrary, cyclic replacement of a certain appropriate volume of blood between the treated periphery (extremity) and the centre of body's haemodynamics (heart), induced by VCT, favourably stimulates the entire circulatory system. In the circulatory system, the VCT application stimulates the effect of light physical training, which has a favourable impact upon the heart (pump) activity (heart haemodynamics).
The left heart chamber performance and pulse heart output are slightly increased, the resistance of systemic vasculature (vasodilatation is induced) is reduced, and heart inotrophy is favourably influenced. The blood pressure is slightly increased in the course of procedure (especially in the positive-pressure phase – analogy of physical training), however, after finishing the procedure, the desirable decrease in blood pressure occurs. These effects can be utilized in supportive treatment of functional systemic circulatory abnormalities in early stages of their development within the framework of primary or secondary prevention (for example, reduced circulatory performance, increased blood pressure, …).

Finally, we can resume the effects occurring during the positive-pressure and negative-pressure phases alternation of VCT:

- The transmural pressure on the capillary wall is changed, and, subsequently, the exchange of gases, oxygen, CO2 and substances (including any pharmaceuticals) between blood and tissues, is improved.
- Due to the drop of peripheral resistance, the collateral blood supply development is supported.
- The higher arteriovenous pressure gradient increases the blood flow circulation in capillaries also during increased blood viscosity or reduced elasticity of erythrocytes.
- The increased venous return, decreased peripheral venous pressure, and increased capillary filtration contribute to a decrease in the thrombotic activity and improvement of lymphatic drainage of tissues.
- A physiological stimulation of the new formation of the capillary bed occurs, including its functionality and performance (possible utilisation of this method in patients with diabetic micro-angiopathies).

Vacuum-compression therapy may be utilised as monotherapy, but primarily, it is an appropriate part of complex therapy. It doesn´t embody contraindications with administration of another forms of physical therapy. Vacuum-compression therapy shows a principal synergism with pharmacotherapy, which is primarily based on the better induction and utilisation of medicinal products to target tissues.

Dietary measures and active movement, if possible, always belong to the basic conceptual framework of treatment.

A basic factor of vacuum-compression therapy is the action of the closed hypobaric air environment upon the treated extremity. The objective of this action is to induce a local passive hyperaemia from the most opened collateral bed, including fully utilised and strengthened collaterals. Significant improvement of perfusion and increased presence of arterial blood in the extremity have also been demonstrated experimentally, using a gamma camera by means of Tc radionuclide-labelled erythrocytes. It has been shown that during the VCT procedure, perfusion was increased approximately 3 times in the negative-pressure stage and 2 times in the positive-pressure stage of vacuum-compression therapy (Fig. 2.2).

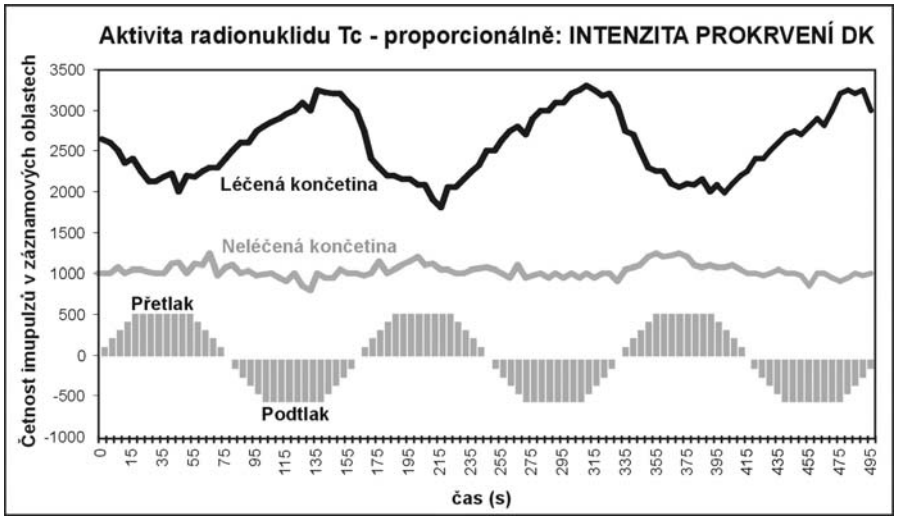


Fig. 2.2: Change in perfusion of the treated and untreated extremity during atypical application of VCT.

The effect of increased amount of arterial blood in the extremity also remains for a long time following the procedure, namely with an approximately 40% increment (Fig. 2.3).

Changes in perfusion of the extremity are also visible on its surface layers. This fact is very important when VCT is used in the treatment of skin defects (such as varicose ulcers or diabetic ulcerations, but also in cosmetic, anti-aging etc.). This fact has experimentally been confirmed by using the „in-vivo“ remission spectroscopy diagnostic method (Fig. 2.4).

Vacuum-compression therapy may also be considered as passive vascular training, in contrast to active training - therapeutic physical training, and movement regimen. Vacuum-compression therapy can also be applied as a highly effective and decisive complement to such active training. VCT undertakes the key role in cases of other serious disorders and polymorbidity which restrain or exclude the possibility of active movement therapy.

During VCT, adequate changes in skin colour of the treated extremity are usually visible, synchronously with the alteration of positive-pressure and negative-pressure phases (see illustrative Fig. 1.3 and 1.4). In the negative-pressure phase, the colour of the skin becomes hyperaemic (purple). This coloration spreads in the distal direction down to the tips of the fingers. If during this negative-pressure stage the generalisation of redness of the extremity is not achieved up to the acrum, it is recommended to prolong the duration of this negative-pressure stage, and, subsequently, to increase the negative pressure. After a given number of negative-pressure, positive-pressure cycles, the purple colour usually turns to clear red. Demonstrations of these colour changes are usually very subtle, therefore, it is necessary to monitor them carefully through the transparent wall of the application cylinder during the procedure. The described course of skin colour changes is, so far, an essential indicator of therapy efficiency during the procedure. If a clearly red marking of the skin is reached,

other sufficiently intensive values of therapeutic biotropic parameters of procedure are selected (positive-pressure, negative-pressure values and duration), and there is no need to increase these values. On the contrary, these values may be decreased. In the event that no colour changes are reached, or these changes are not sufficient during the procedure, then it is advisable to increase the values of the main therapeutic parameters, if possible. However, it must be taken into consideration that during VCT application the optimal colour changes are most quickly and best expressed with healthy persons. In patients with vascular disorders, the required response may happen only after repeated procedures, not immediately after administration of first procedures. This colour change may be so small that it cannot be perceived by the naked eye, but the procedure may bring the needed therapeutic benefit. Therefore, it is not appropriate to increase the values of particular parameters, or even to replace a used therapeutic program for a more radical one immediately during the first procedures, eventually to stop the administration of VCT procedures, in case the colour changes on extremity are not visually visible.

If it is necessary to increase the parameters of VCT, we recommend prolonging the positive pressure, negative-pressure phases first. The pressure values of these stages are to be subsequently increased gradually, and always with care.

A limit for the selection of VCT parameters should be based on the individual condition of a particular patient with respect to the condition of his/her vascular bed, and in relation to contraindications and possible risks of VCT. Attempting to reach the optimal colour changes is not the only criterion for effective and safe VCT. During the VCT procedure, the importance of cyclic application of a positive-pressure phase, preferably longer, must not be left out of consideration. The purpose of this positive-pressure phase is, in particular, to force out the blood volume (or lymph or tissue liquids) taken in during the previous negative-pressure (hypobaric, hyperemising) phase so that this blood may be replaced by a new volume of fresh blood, bringing oxygen, or other necessary nutritional substances, or pharmaceuticals, in a subsequent cycle of VCT. So, failure to meet this requirement may act against the principles of VCT!

For objectivisation of administration of VCT procedures is the watching of colour changes of the treated extremity very indispensable but only feeble aid. There is a device, which called “Pacient monitoring” (see further) , which is an optional additional device for VCT therapy type Extremiter 2010 “Better future” edition. It enables to create such as variant of the device, which provides the possibility to watch the immediate reaction of the pacient on the administrated procedure of VCT. It is possible because of the objective and valid exact measurement:

- the extremity volume monitoring (V)
- vascularisation and arterial blood oxygen saturation monitoring (SpO2)
- perfusion index (PI)

Prescription, monitoring, and evaluation of VCT results may be carried out only by an experienced and responsible physician. VCT procedures may be carried out by trained health-service personnel, or by physiotherapists. Utilisation of VCT for reconditioning, sports, and cosmetic purposes can be done only in co-operation with a physician.

Fundamentals for the use of negative pressure, positive-pressure stages during VCT ensue from physiology of their effects. A higher value of „deep hyperemising“ negative-pressure is to be selected for arterial circulatory disorders and their stagnant metabolism. Values of positive-pressure must be able to ensure corresponding venous drainage.

In the case of combined arterial and venous disorders, it is advisable to increase the value of positive pressure on an individual basis. This value, however, must not exceed the negative pressure.

With dominative oedema of venous or lymphatic origin, the positive-pressure can be set-up up to the double value of negative-pressure. The negative-pressure phase must be longer than the positive-pressure phase.
In most cases it is possible to choose the prescript for VCT procedure from the software of the Extremiter device. With a view to this is in the device pre-programmed the folder “Procedures according to Diagnoses”. This folder contains cca 500 procedures of VCT, they are classified according to indicated diagnoses. That means, that the folder is a very exact and well arranged list/ encyclopedia.

The reaction of the pacient on the administrated procedure can be very individual and untypically, it can diverse on each sitting. As it is in the folder “Procedures according to Diagnoses” preprogrammed and hierarchic classified 500 procedures with very proper parametres. (these are based on the 20 years of researching of VCT) the procedure can´t be the most optimal for each pacient and each situations. The best solution is to use all additional devices, above all the Pacient monitoring. This addition enables to watch each reaction of the pacient while using the VCT.

In setting the appropriate time parameters (periods of duration) for both phases (positive pressure / negative pressure)
it is advisable to take a reverse ratio of (maximum) pressure values of these phases for rough orientation. This means how many times the absolute value of negative-pressure (in kPa) is higher (lower) than the absolute value of positive-pressure, so many times the duration of this phase will be shorter (longer).

Note: As duration (in seconds) is understood the time for which the maximum (set-up) pressure phase value is held, and it does not mean the period that is necessary for transition from one phase to other.

In the case of combined arterial and venous disorders, the usual values of positive pressure / negative-pressure range from +/- 3 up to 6 kPa. In the case of mostly arterial disorders, this negative-pressure can be set within the range of - 6 kPa up to - 12 kPa. The stronger negative pressure is selected only in exceptional cases, such as scleroderma and more serious stages of arterial disorders with certain complications. In such cases, however, all relevant risks and contraindications of VCT must be carefully considered. Higher values of negative-pressure are also often connected with worse subjective toleration by the patient.

The amount of negative-pressure, especially its duration, is usually selected so that the rising passive hyperaemia would be able to extend into the tips of the extremity during this negative cycle phase. In the event of bad tolerance and risks of using the higher value of negative-pressure, this pressure can be reduced to below its usual value, and partially compensated by a longer period of its action.

In antioedematous therapy, the positive-pressure can be increased up to the values ranging from + 6 kPa up to +10 kPa. The positive-pressure is used to be better tolerated by the patient, but, theoretically, its risk (mainly thrombosis) is the same, or even higher, than the risk resulting from the negative-pressure application. The combination of higher positive-pressure with lower negative-pressure is also suitable for the treatment of local painful conditions associated with the oedema without organic vascular affection, such as algodystrophic syndrome, and for the treatment of some post-traumatic conditions. Once the oedema is under control, you can use positive-pressure, negative-pressure symmetric values.

Duration of the VCT procedure ranges from 20 minutes up to 30 minutes as the minimum in order to perform at least 10 positive-pressure, negative-pressure cycles during this procedure. In individual and well-founded cases, this procedure may take a very long time. Nevertheless, care must always be taken with regular interruptions of the procedure, or it is necessary to monitor appearances of imminent callus, along with the patient’s comfort.A long-term procedure may also be divided into several shorter procedures, performed during a single day.

At the beginning of treatment, VCT is usually applied daily, then three times a week, twice a week, or once a week (maintenance treatment). In indicated cases, the VCT procedure may be performed for a longer time, or repeatedly.

During VCT applications, the patient must comfortably and safely sit on a stable armchair or chair. Optimally, the armchair should have a higher placed sitting area, adjustable back rest (preferably while treating the under extremity, the patient should be in a half sitting / half lying position, while treating the upper extremity, the pacient should sit in upright form, solid elbow and head rests, if possible. It is very important, that the armchair enables a movement to the left and right, because only by this way it is possible to insert the treated extremity exactly to the centre of the application cylinder. VCT

procedures can also be administered to the patient in lying position on bed or couch. In doing so, it is necessary to ensure carefully the patient's stable position (prevent his/her falling from the bed in the course of treatment).

Prima facie evidence of VCT efficiency using the EXTREMITER is increased by a device enabling variable pressure changes in the sealing cuff of the device. The necessary pressure in the sealing cuff, ensuring a hermetic seal of the treated extremity, is controlled fully automatically with a feedback. The optimum sealing pressure follows dynamically pressure changes in the application cylinder. Therefore, the treated extremity is not strangulated by the cuff.

As every really effective therapy, vacuum-compression therapy has some risks and contraindications. Its prescription may be given only by a physician. A typical prescription of VCT must contain a localisation of a treated part of the body; negative/positive-pressure values, duration of maximum pressure phases, or identification of therapeutic program, patient's position during treatment (sitting/supine), procedure duration, total number of procedures in a series, number of therapeutic series in a year, and the like. When administering VCT procedures, the clinical view is necessary. Therefore, it is necessary to individualise therapeutic parameters also during treatment according to the patient's actual condition.For this purpose is optimal to use the additional device type "Pacient monitoring", its meaning was described above. In case the doctor working at another working place want to use the control diagnostic system, there is a possibility to use the another additional device type designation "PC supervision". It is a optional additional device of the device for vacuum-compression therapy Extremiter 2010 Better Future edition, which enables to create such as model of the device, which provides the possibility of control, evidence and controling of the procedures by the help of distant PC, interconnect wireless or interconnect with the control PC.

The base of the technical solution of this additional device ***PC supervision*** is the securing of the communication between the device´s control PC and the supervising PC, which provides to the doctor or to another medical worker the possibility to control and file the administrated procedure of VCT. By this way will be the quality, the efficiency, the suitability and lást but not least the safety of the administration of VCT. The additional device type PC supervision provides to the medical worker to watch the process of the VCT, the reaction of the pacient in real time. The doctor can also trench into the procedure during the administration of VCT, it is also possible to change the parameters to ensure the most optimal conditions of VCT procedure. Simultaneously the additional device ensures the duplicity of the databases of the administrated VCT procedure, the possibility of improving the quality of the procedure´s prescription, composition of the procedures directly on the supervising PC and subsequently sending this to the control PC of the device. It is also possible to analyse the results except the real time. In order to use the telemedicine through the internet.

The prescription, the special monitoring and the evalutation of the VCT therapy´s results can be naturally provided only by the qualified doctor. The proper VCT therapy administration could be provided only by the trained medical worker or physiotherapist or the doctor. The using of VCT for recondition and sports purposes is possible only in co-operation with the doctor.

At using the additional device type "Pacient monitoring" is possible to controlduring administration of procedure and control the paramtres of the procedure in two modes. The first is a standard mode, where it is not displayed the reaction of the pacient, but only the overpressure and underpressure in the application cylinder. The second mode will be invoked by pressing the click on the "graph" pictogram in left bottom part of the display. Here are depictured the reaction of the pacient. In left part of the graph are displayed the appropriate axes and its gauges for each measured quantity. Each axe appertains to in color to measured quantity.

- blue graph means the size of perfusion index PI
- red graph means the blood saturation with oxygen
- green graph means the volume change of the extremity
- black graph means the size of the healing pressure

The additional device for Simultaneous application of carbon dioxide – to another improvement of better blood circulation:

As the accessory to the device Extremiter 2010 Better Future edition is possible to use the additional device CO2 Therapy (see the User´s manual). The application cylinder is is filled not only with air, but medical carbon dioxide is supplied into the cylinder in order to achieve the desired therapeutic concentration.

Carbon dioxide has a specific effect on capillaries and receptors. This effect is especially valuable because it is transcutaneous and direct, resorbed through the skin, and its therapeutic effect is not necessary to mediate using often precariously functioning mediators of neural transmission. Absorbed carbon dioxide opens functionally narrowed or closed capillaries, releases precapillary sphincters, shifts the oxyhemoglobin dissociation curve to the right, and reduces blood viscosity.

On the general connection schema you can see, that the ground of the technical solution of the additional device type CO2 Therapy edition „Better Future“ is the control and mixing unit, which ensures the mixing of carbon dioxide with the air on the requiered and indicated concentration (see the display concentration measurement and control in the bottom part of the unit), so the disinfection of the recycling mixture of the air and carbon dioxide in the requiered concentration. This basic unit of the electronic controlled mixing unit regulates automatically the supply of the fresch medicinal carbon dioxide from the pressure tank – CO2 bottle.

The pressure on the output with CO2 is appropriately reduced by the safety, two-stage reduction valve, its output is by the staff manual adjusted on the pressure circa 0,2 till max. 0,5 bar. The pressure tank with carbon dioxide can be transport only with properly ensured by the safety way (see

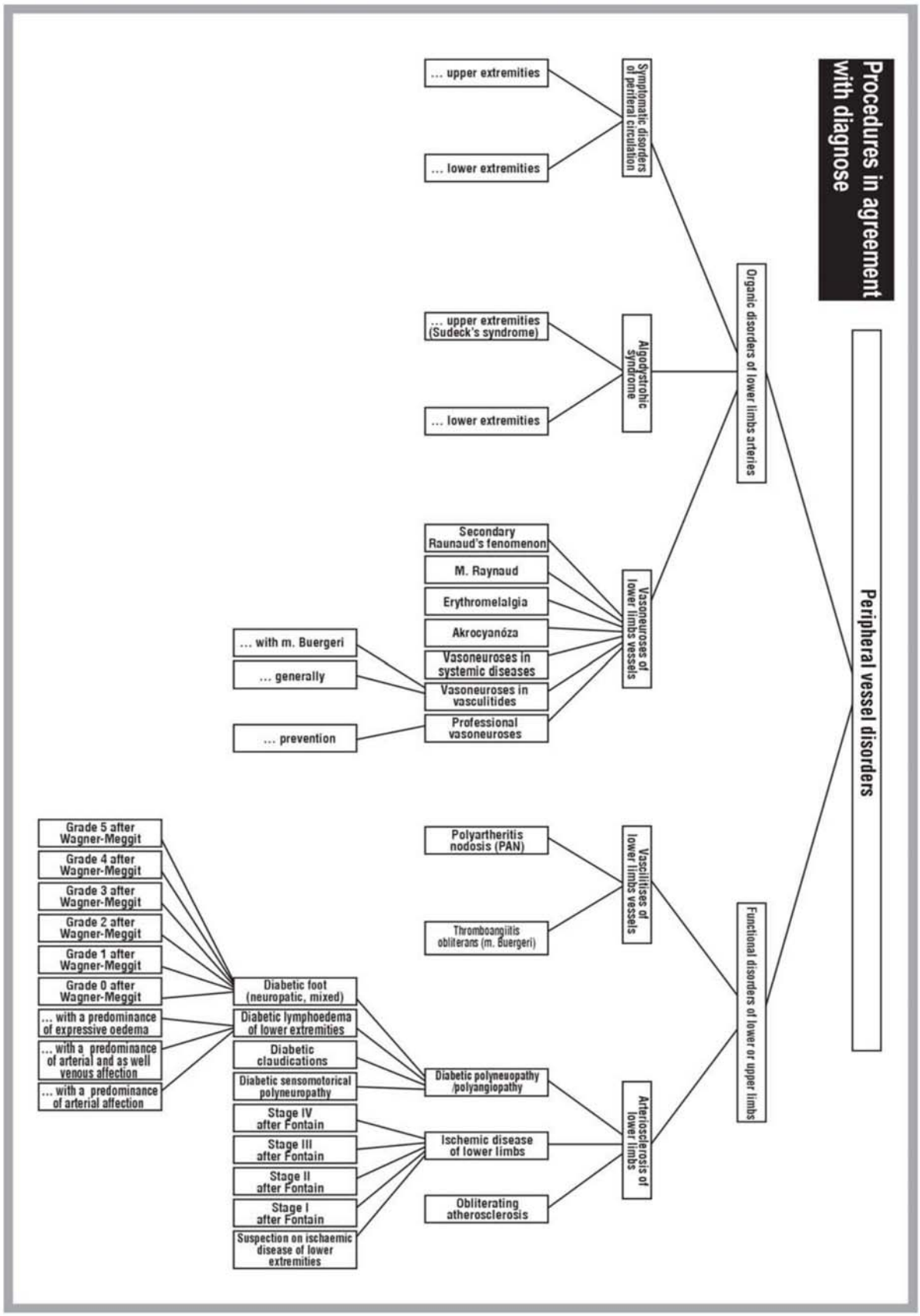
the picture the trolley with the chain) and by the same way should be ensured the pressure tank on the place with the device for vacuum-compression therapy. Low-pressure hose connections connect the tank pressure with control and mixing reservoir and the mixing reservoir with the own device for vacuum-compression therapy. In case the device is provided by the HEPA filters class P3, than are these filters screwed up and into their connection places are putted the hoses from the mixing reservoir. This mixing reservoir is equipped proper two HEPA filters and one metal rustless cylinder covered by efficient germicidal lamp, which cares with the HEPA filters about the effective disinfection of the gasous medium air with CO2 with regard to the pacient, with regard to the environment.
The device can be used without the carbon dioxide also to the effective disinfection of the recycling gaseous medium (most often) used in application cylinder of the device for vacuum-compression therapy.

2.7.2 Indications of Vacuum-Compression Therapy Procedures

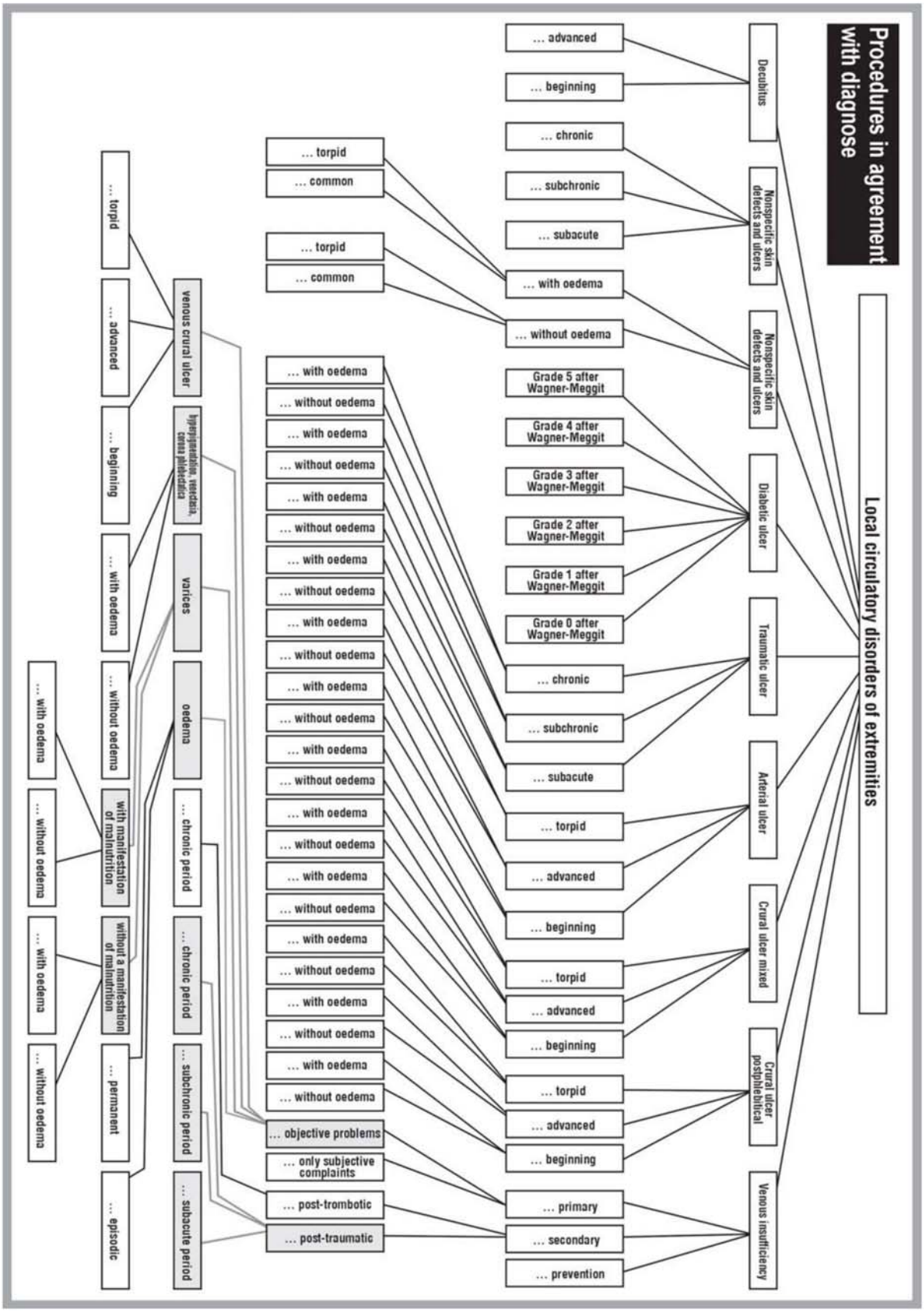
It is the exclusive responsibility of a qualified physician to decide about the administration of therapeutic VCT procedures and selected program, or parameters of procedure for the treatment of a particular diagnosis and particular patient. The following data were approved in the process of clinical evaluation of the device, however, they have only a supportive and information nature. The pre-programmed parameters of these procedures are preliminary only, and if used with a particular patient, their verification by a physician is necessary, along with subsequent monitoring of patient's response to the given therapy (see the information in previous chapter)

2.7.2.1 Procedures indicated according to diagnoses

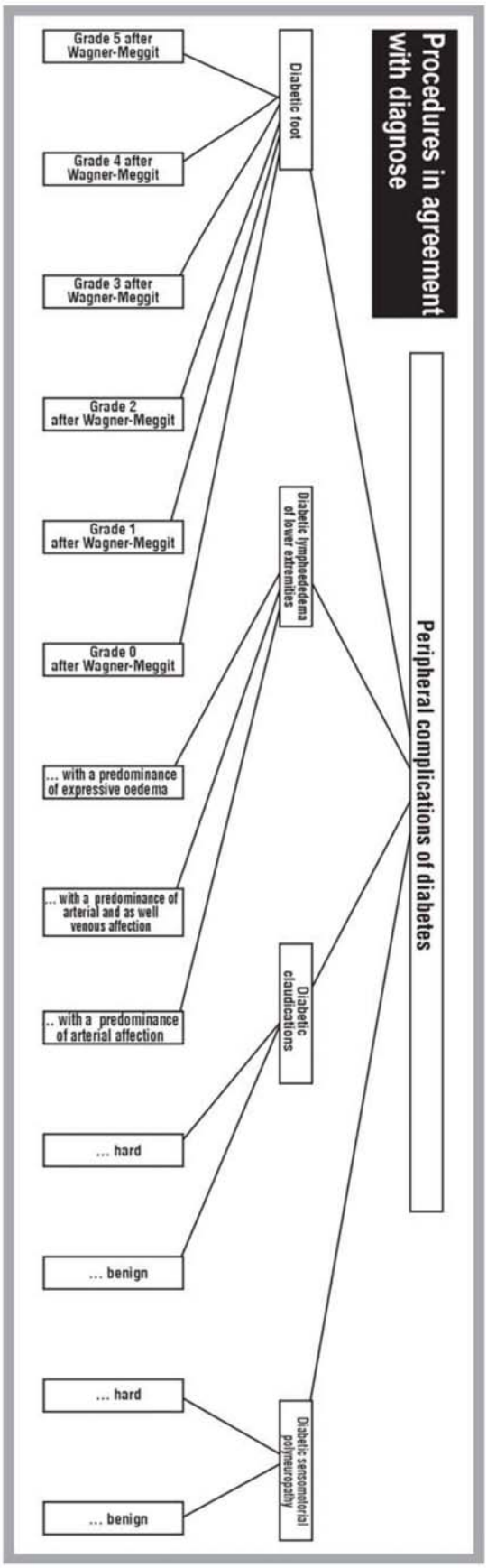
Group 1: Peripheral vessel disorders:


Procedures in agreement with diagnose
Peripheral vessel disorders
Organic disorders of lower limbs arteries
Functional disorders of lower or upper limbs
Symptomatic disorders of periferal circulation
... upper extremities
... lower extremities
Algodystrohic syndrome
... upper extremities (Sudeck's syndrome)
... lower extremities
Vasoneuroses of lower limbs vessels
Secondary Raunaud's fenomenon
M. Raynaud
Erythromelalgia
Akrocyanóza
Vasoneuroses in systemic diseases
Vasoneuroses in vasculitides
Professional vasoneuroses
... with m. Buergeri
... generally
... prevention
Vasculitises of lower limbs vessels
Polyartheritis nodosis (PAN)
Thromboangiitis obliterans (m. Buergeri)
Arteriosclerosis of lower limbs
Diabetic polyneuopathy /polyangiopathy
Ischemic disease of lower limbs
Obliterating atherosclerosis
Diabetic foot (neuropatic, mixed)
Diabetic lymphoedema of lower extremities
Diabetic claudications
Diabetic sensomotorical polyneuropathy
Stage IV after Fontain
Stage III after Fontain
Stage II after Fontain
Stage I after Fontain
Suspection on ischaemic disease of lower extremities
Grade 5 after Wagner-Meggit
Grade 4 after Wagner-Meggit
Grade 3 after Wagner-Meggit
Grade 2 after Wagner-Meggit
Grade 1 after Wagner-Meggit
Grade 0 after Wagner-Meggit
... with a predominance of expressive oedema
... with a predominance of arterial and as well venous affection
... with a predominance of arterial affection

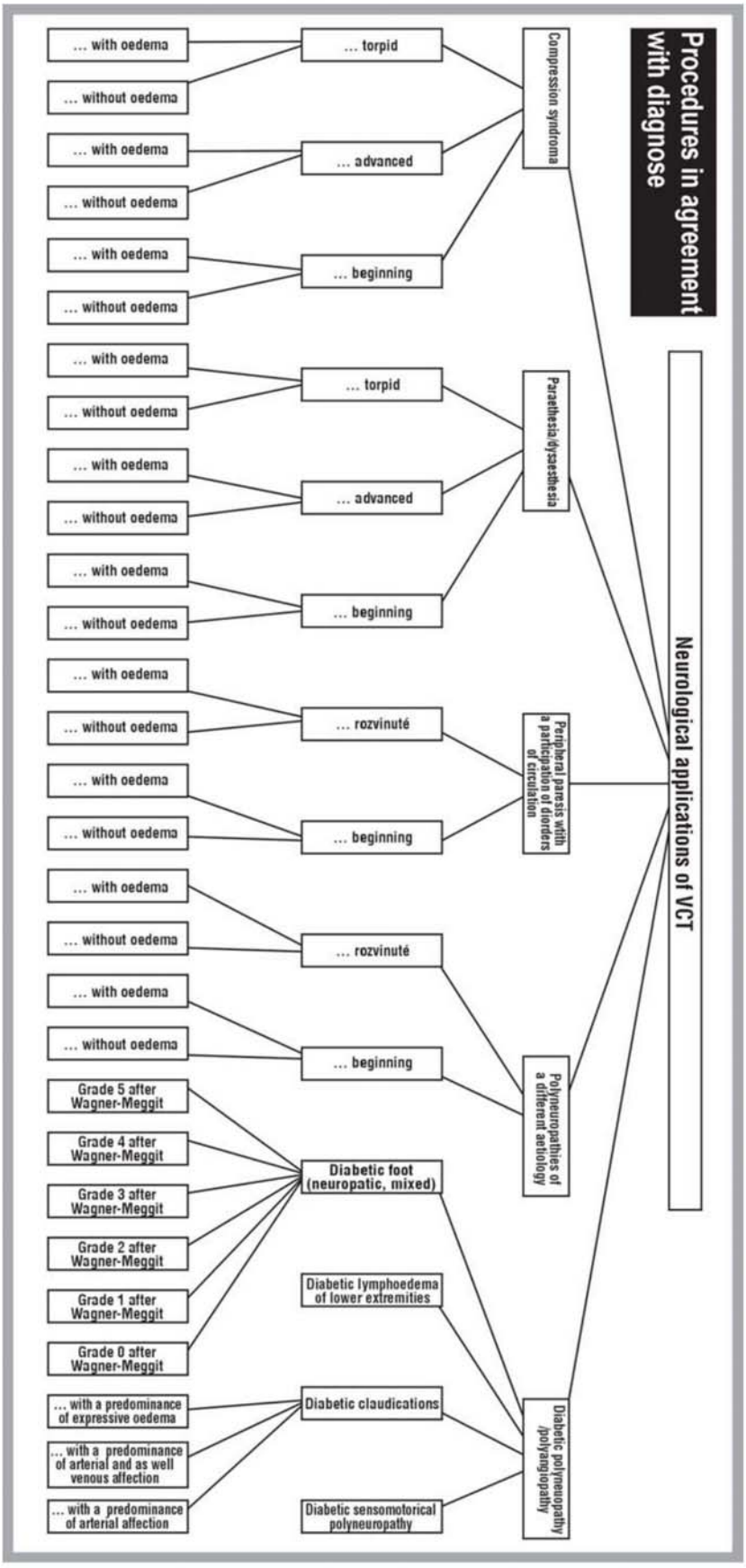
Group 2: Local circulatory disorders of extremities:



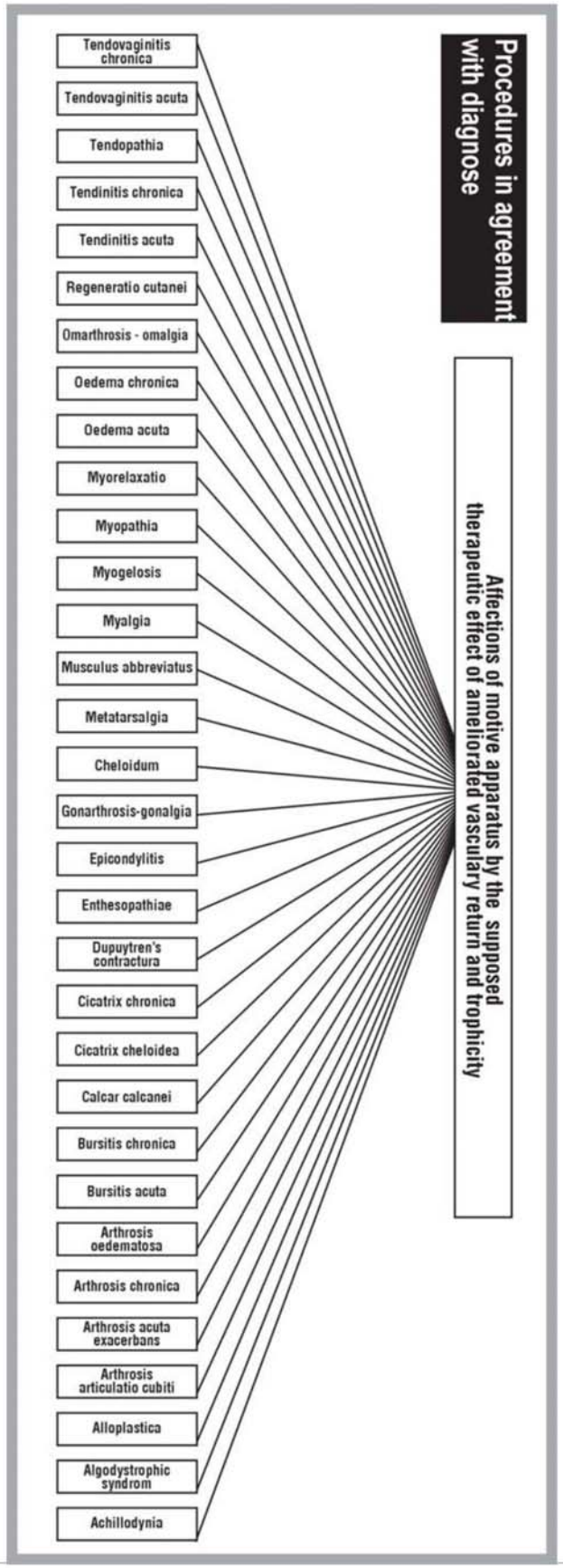
Group 3: Peripheral diabetic complications:


Procedures in agreement with diagnose
Peripheral complications of diabetes
Diabetic foot
Grade 5 after Wagner-Meggit
Grade 4 after Wagner-Meggit
Grade 3 after Wagner-Meggit
Grade 2 after Wagner-Meggit
Grade 1 after Wagner-Meggit
Grade 0 after Wagner-Meggit
Diabetic lymphoedoedema of lower extremities
... with a predominance of expressive oedema
... with a predominance of arterial and as well venous affection
.. with a predominance of arterial affection
Diabetic claudications
... hard
... benign
Diabetic sensomotorial polyneuropathy
... hard
... benign

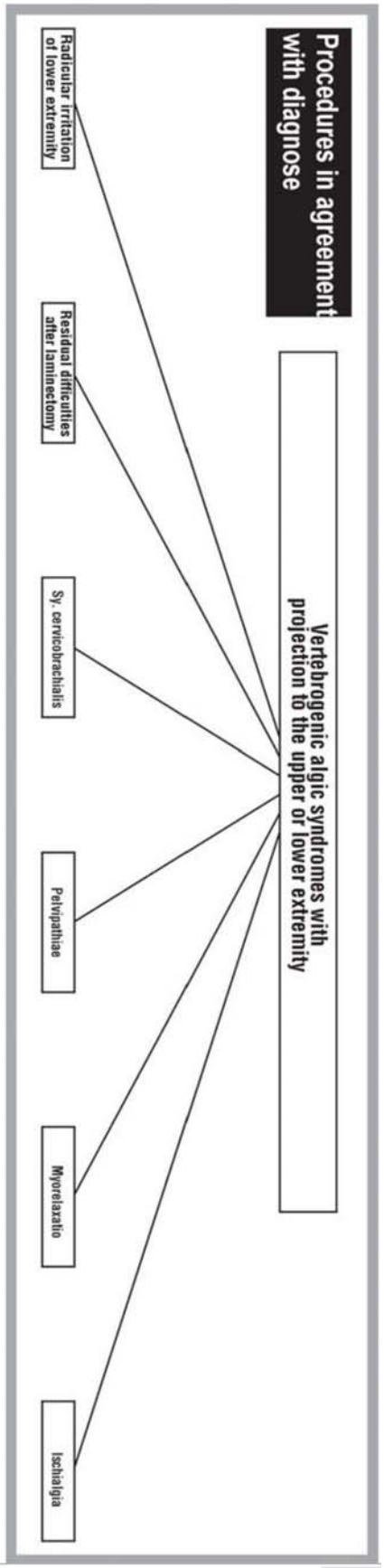
Group 4: Neurological diabetic complications:


Procedures in agreement with diagnose
Neurological applications of VCT
Compression syndroma
Paraesthesia/dysaesthesia
Peripheral paresis with a participation of disorders of circulation
Polyneuropathies of a different aetiology
Diabetic polyneuropathy /polyangiopathy
... with oedema
... without oedema
... torpid
... advanced
... beginning
... rozvinuté
Grade 5 after Wagner-Meggit
Grade 4 after Wagner-Meggit
Grade 3 after Wagner-Meggit
Grade 2 after Wagner-Meggit
Grade 1 after Wagner-Meggit
Grade 0 after Wagner-Meggit
Diabetic foot (neuropatic, mixed)
Diabetic lymphoedema of lower extremities
Diabetic claudications
... with a predominance of expressive oedema
... with a predominance of arterial and as well venous affection
... with a predominance of arterial affection
Diabetic sensomotorical polyneuropathy

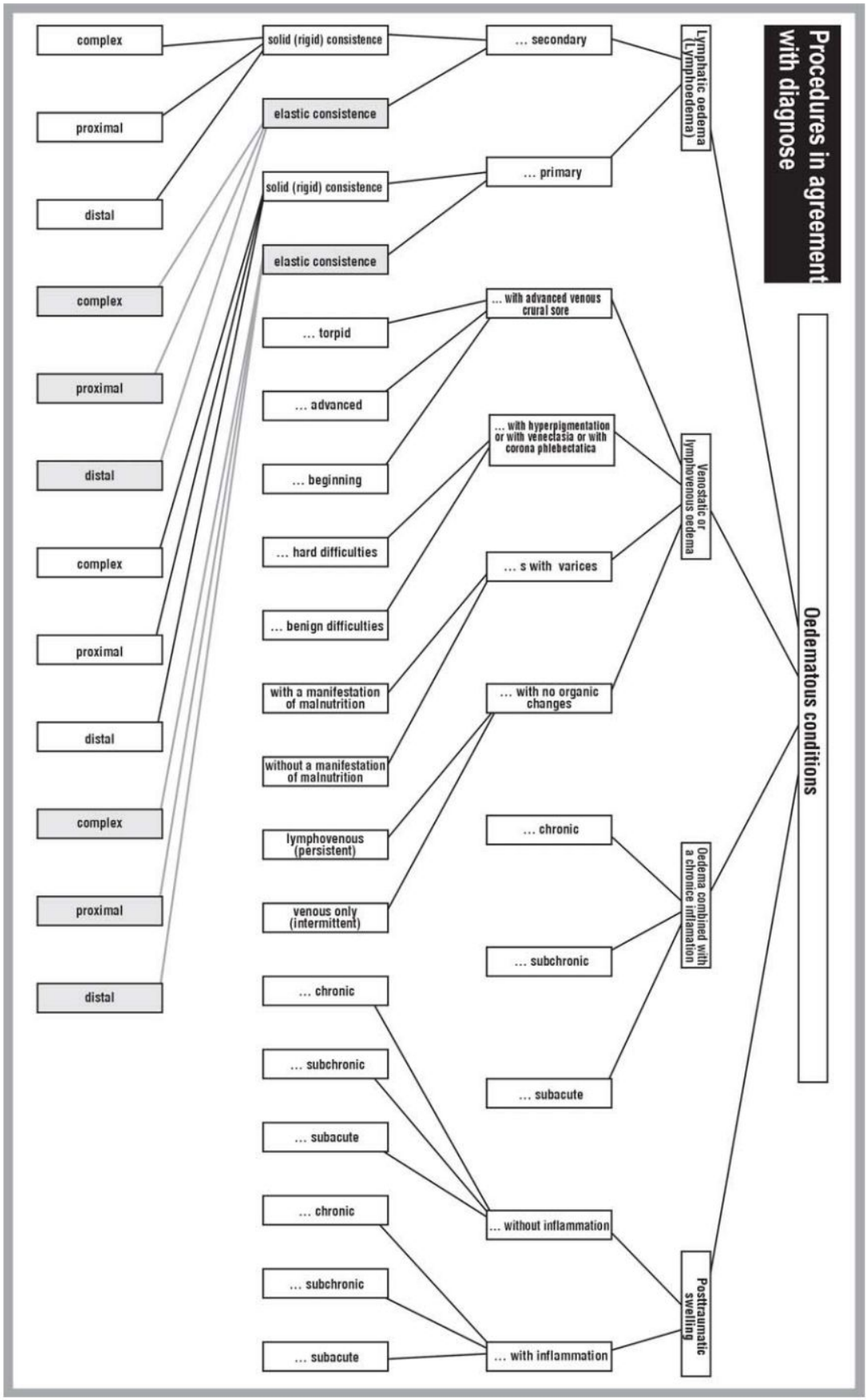
Group 5: Disorders of movement system of extremities with expected therapeutical effect of improved profusion and trophism in tissues:



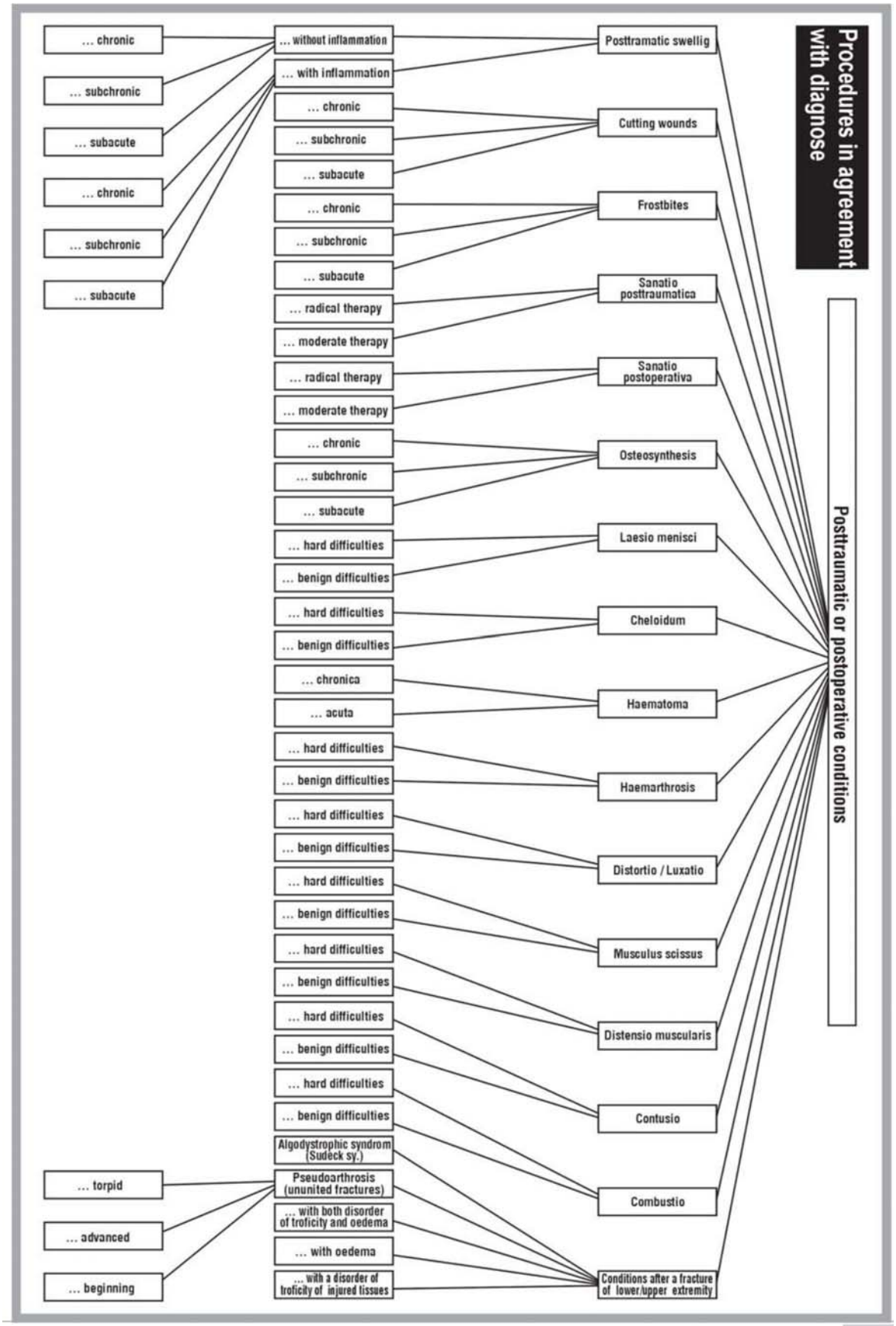
Group 6: Vertebrogenous algic syndromes with projections to the upper extremity, or lower extremity:



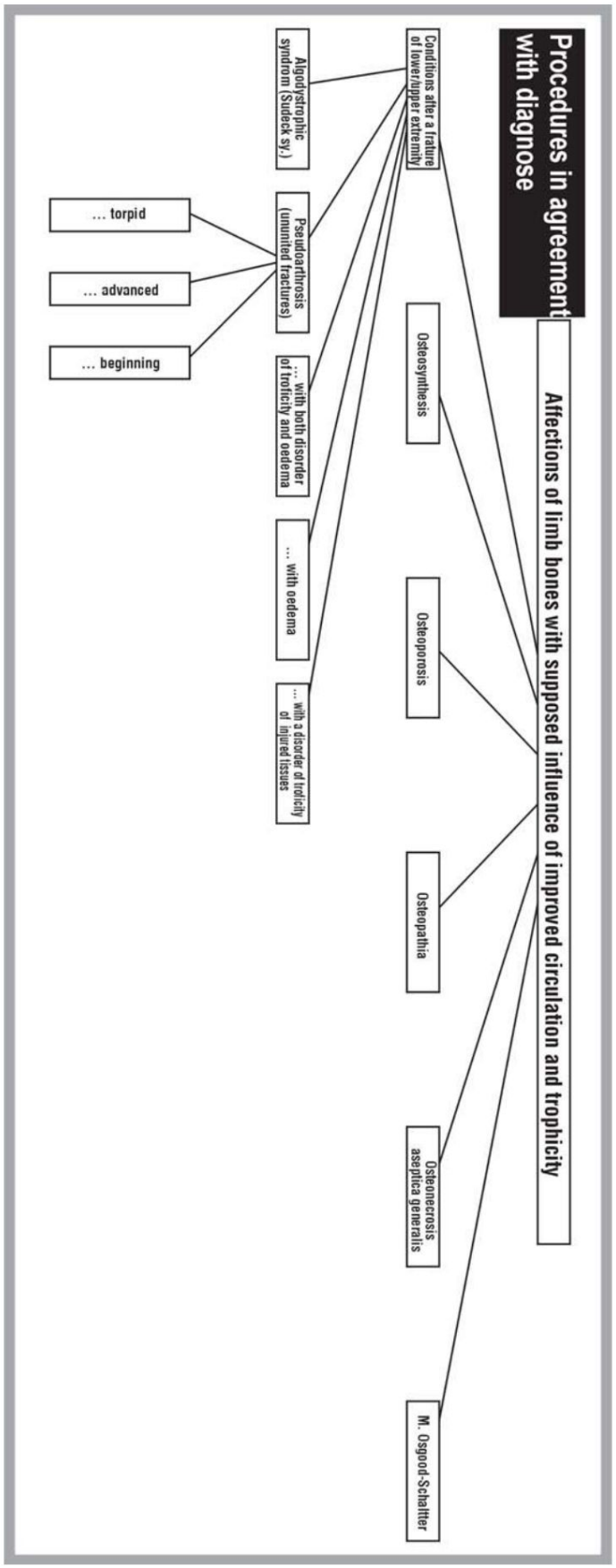
Group 7: Oedematous conditions:



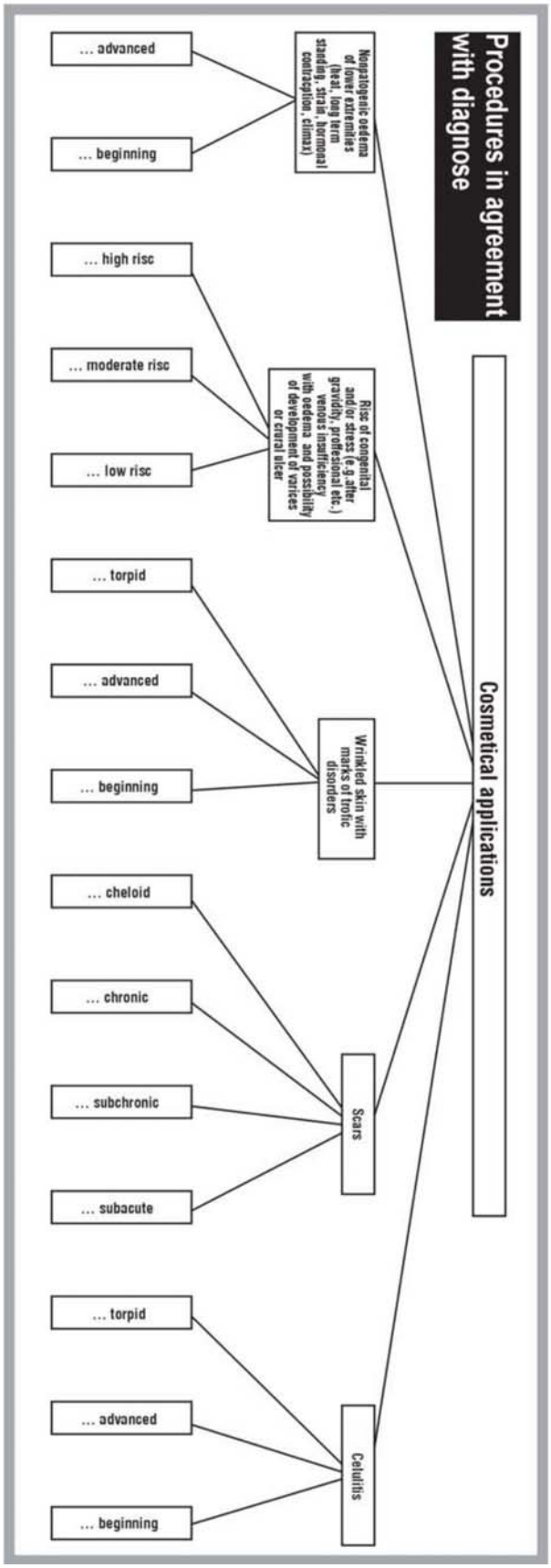
Group 8: Post-traumatic and post-surgery conditions:



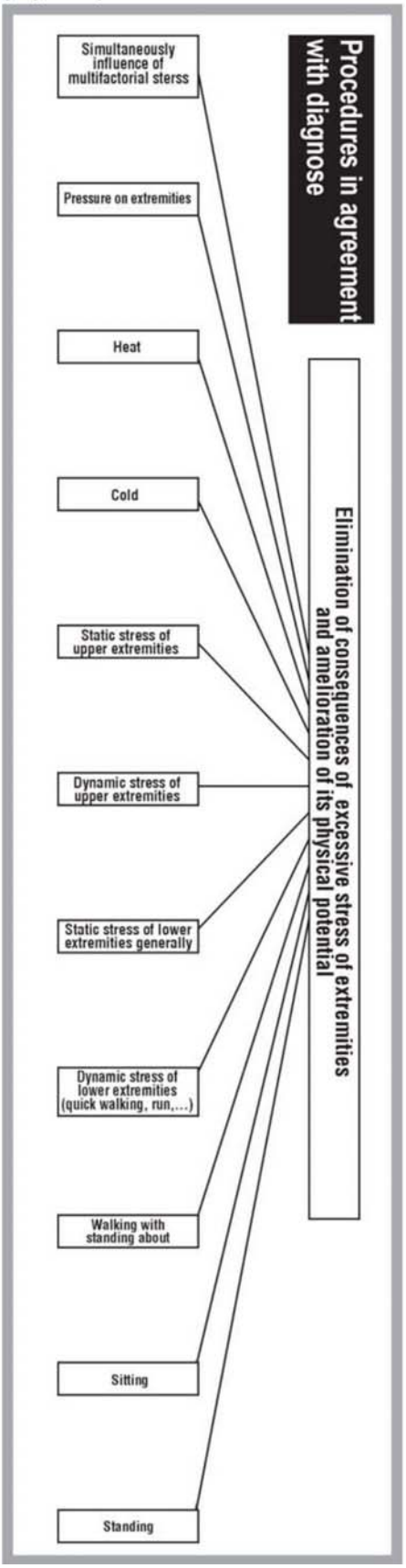
Group 9: Bone disorders of extremities with an expected therapeutical effect of improved profusion and trophism in tissues:


Procedures in agreement with diagnose
Affections of limb bones with supposed influence of improved circulation and trophicity
Conditions after a frature of lower/upper extremity
Algodystrophic syndrom (Sudeck sy.)
Pseudoarthrosis (ununited fractures)
... torpid
... advanced
... beginning
... with both disorder of trofiicity and oedema
... with oedema
... with a disorder of trofiicity of injured tissues
Osteosynthesis
Osteoporosis
Osteopathia
Osteonecrosis asepitica generalis
M. Osgood-Schlatter

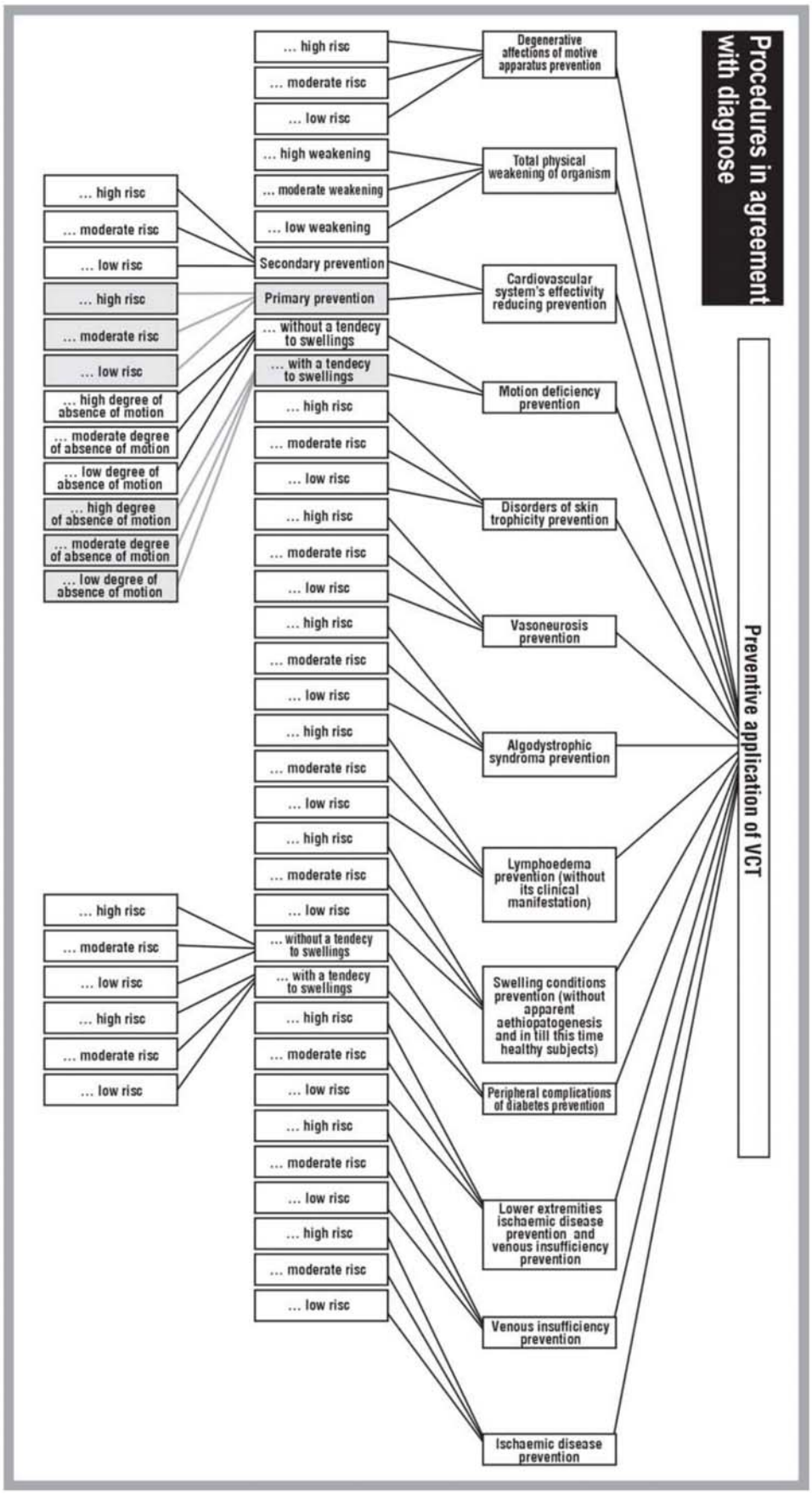
Group 10: Cosmetic applications:



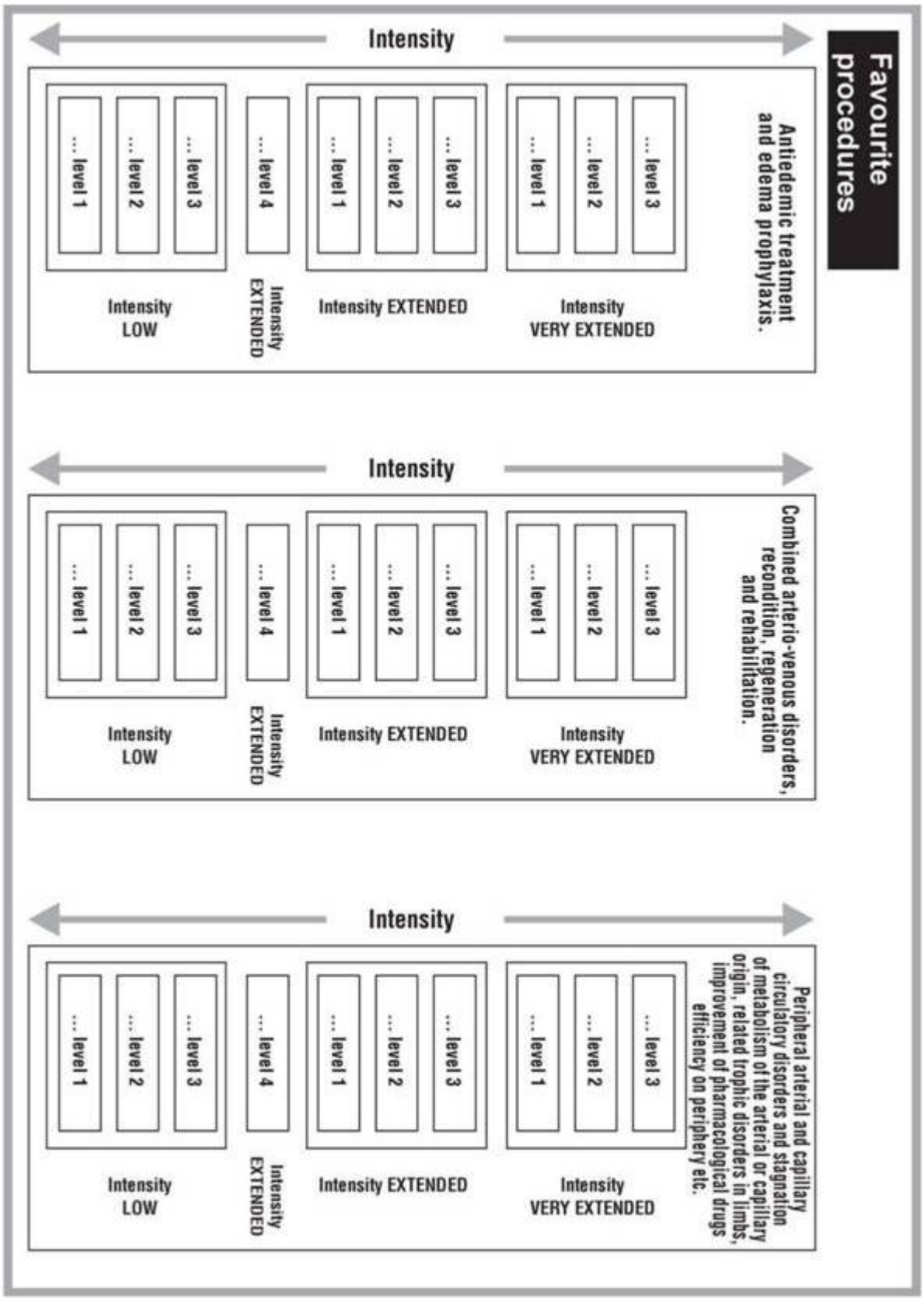
Group 11: Elimination of consequences of excessive stress of extremities, and increase of their physical potential:


Procedures in agreement with diagnose
Elimination of consequences of excessive stress of extremities and amelioration of its physical potential
Simultaneously influence of multifactorial sterss
Pressure on extremities
Heat
Cold
Static stress of upper extremities
Dynamic stress of upper extremities
Static stress of lower extremities generally
Dynamic stress of lower extremities (quick walking, run,...)
Walking with standing about
Sitting
Standing

Group 12: Preventive use of VCT:


Procedures in agreement with diagnose
Preventive application of VCT
Degenerative affections of motive apparatus prevention
Total physical weakening of organism
Cardiovascular system's effectivity reducing prevention
Motion deficiency prevention
Disorders of skin trophicity prevention
Vasoneurosis prevention
Algodystrophic syndroma prevention
Lymphoedema prevention (without its clinical manifestation)
Swelling conditions prevention (without apparent aethiopatogenesis and in till this time healthy subjects)
Peripheral complications of diabetes prevention
Lower extremities ischaemic disease prevention and venous insufficiency prevention
Venous insufficiency prevention
Ischaemic disease prevention
... high risc
... moderate risc
... low risc
... high weakening
... moderate weakening
... low weakening
Secondary prevention
Primary prevention
... without a tendecy to swellings
... with a tendecy to swellings
... high degree of absence of motion
... moderate degree of absence of motion
... low degree of absence of motion

2.7.2.2 Procedures indicated according to formerly, exclusively used well-proven procedures



2.7.3 Contraindications of Vacuum-Compression Procedures

Vacuum-compression therapy is demonstrably a highly effective form of physical therapy applicable in many fields of medicine. As every really effective therapy, it also has some contraindications, risks, and possible side effects. Knowledge about them is developing; for example, new unknown contraindications may appear, or, on the contrary, some current contraindications may be shown as too strict or unnecessary.

It is the natural duty of the user of this device, and a responsible organisation, to follow the development of this knowledge throughout the use of the device.

According to the current professional medical knowledge, the following conditions are considered to be VCT contraindications:

- **Acute conditions of venous thrombosis and embolism, and suspicion of them!**
- **Aneurysm in the area of the treated extremity (a risk of microembolism from the local thrombus)!**
- **Severe haemorrhagic diseases and radical anticoagulation treatment**
- **Acute open wounds with a risk of bleeding and development of subcutaneous emphysema.**
- **Local septic infections with a risk of dissemination of infectious agents and toxic products.**
- **Local malignant tumours in cases of existing risks of dissemination of tumour metastases.**
- **Advanced necrosis (gangrene) with a risk of toxic decomposition substance mobilisation into the circulation.**
- **Oedemas of extremities with a cardiac origin.**
- **Leyden syndrome.**
- **Gravidity (relative contraindication can be taken into consideration in treatment of lower extremities primarily in more advanced stages of gravidity.**
- **Increased trend to petechias and haematomas at the place of hermetic sealing of the extremity (pressure induced by the sealing cuff or neck edge of the application cylinder).**
- **Psychical disorders not allowing closure of the extremity in the applicator.**

On principle of any therapeutic method, the above-mentioned contraindications list cannot be considered exhaustive. The patient's overall condition must also be taken into consideration. For example: universal arteriosclerosis, a stage of the ischemic heart disease, serious disorders of the myocardium due to other reasons, septic states, hyperthermia, serious hypertension with complications, serious orthostatic hypotension, cachexy, susceptibility to phlembotromosis or thrombophlebitis, the genetic load (for example, presence of the Leyden syndrome), the use of contraceptives by women, and the like.

VCT procedures may be indicated only by the physician.

If in doubts concerning the presence of the thrombus in vessels of the extremity to be treated, a pre-application examination excluding this possibility should be done before the VCT application!

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3 Technical Description of the Device

3.1 Description of the Device Assembly

The vacuum-compression cylinder (1), which comes into contact with the patient's body, is mounted on a design attractive supporting arch of „shark fin" type" (2), and moved upwards and downwards along this arch by means of a remote controlled, motor-driven mechanism with a reliable and absolutely safe chain transmission. Movement of the application cylinder (1) up or down is controlled by the touchscreen (13) of the control PC, some models of this device could be remote-controlled (11). position UP - 11a, position DOWN - 11b.

The supporting arch of "shark fin" type (2) is anchored in a robust base of the device (3). Inside this base, there are well-arranged and positioned power and control elements of the device (a special multi-chamber compressor with a high performance pump, power supply network section with a safety transformer of health grade and electric filters, valve unit for high volume air flow with a long lifetime, control electronics of power elements, module with AD and DA converters with control microprocessor, motor with worm-planetary gear sets to ensure movement of the application cylinder, toothed gearbox, chain wheels and chain transmission, linear guide of the supporting arch (2), electromagnet and steering rack of the brake, pneumatic distribution systems, air suction filter, measuring and calibration points of electronics, measuring and calibration points of pneumatics, and the like). The vertical supporting arch of "shark fin" type (2) can be easily relocated in the direction of the application cylinder axis in a length of approximately 300 mm. The required position is perfectly fixed using a latch and steering rack, whose stroke (brake release) and brake application functions are remote controlled by means of a powerful electromagnet (from the Touchscreen, or remote control 11: position ON - 11aa - brake released, position OFF 11bb – brake applied). The application cylinder itself (1) is placed on a separate linear guide – horizontal beam (4), which enables further movement of the application cylinder in the direction of its axis, namely in a length of 350 mm. This separate linear guide is also used as a beam (4) of the application cylinder (1).

In real-life situations, one or the other type of feed/movement can be utilized: either with the entire supporting arch (2), or with the separate linear guide (4); possibly, both types of feeds can be superposed. This ensures comfortable insertion – putting the upper and lower extremity into the application cylinder, also in the case of a tall patient with an immobile extremity and limited mobility in the area of hips, knees, or elbows. The separate linear guide of the application cylinder (4) is manually controlled and locked using the "Dual" type handle (5).

The application cylinder (1) is fixed on its horizontal beam (4) by means of supporting (7a) and closing (7b) arms provided with rubber silent blocks, among which is firmly pressed and fixed after pressing the holder (16) and subsequent retraction of „Dual" type handles (24a, 24b). The treated extremity can be inserted, and procedure administered, only in this way fixed position of the cylinder (1). The application cylinder (1) can also be tilted (within the meaning of elevation or depression of the cylinder neck). This tilting is performed by means of a mechanical turn mechanism (6), driven by another separate motor with a straddle gearbox and lever mechanism. Tilting of the application cylinder is also remote-controlled – using the remote control 11: position UP (neck upwards) - 11aaa, position DOWN (neck downwards) – 11bbb. Tilting of the cylinder is very important, primarily from the view point of finding the optimal position of the treated extremity towards the application cylinder, mainly when passing the extremity through the application cylinder neck (8). In this neck, the sealing inflatable cuff (9) is placed, and this must uniformly and tightly fit around the extremity. In doing so, the set-up of height and slope of the application cylinder (1) with regard to the treated extremity significantly facilitates the work of a device operator, and, at the same time, contributes to the optimal administration of VCT procedures. In case we are working with devices, which are using the remote control (11), it is necessary to be near the device.

The application cylinder (1) has a removable bottom (10) fixed by four „Dual" type handles (17) placed around its circumference. Removal of the bottom (10) of the application cylinder (1) is convenient mainly when cleaning or disinfecting the internal environment, or during adjustment of extremity's position in the cylinder, or when sensors of biological quantities of diagnostic instruments are put on the patient's extremity.

The device is intended for power supply 230 V/50-60 Hz and it is constructed in the el.class I. Through its robustness and efficiency the supply is only 220 W, **it is very necessary the device is connected to the electrical power network only through UPS (Uninterruptible Power Suply), which is delivered as a part of the device.**

The control and actuating unit of the device EXTREMITER 2010, „Better Future“ edition is a highly resistant computer of industrial standard, placed in the upper control box (12). The touch screen of this computer (13) is intended for displaying control and check tasks of VCT procedure, and for the control in a touch mode.

The entire device is mobile on four freely design turning travelling wheels (14) provided with foot brakes (14a).

Brakes of travelling wheels are accessible as foot brakes. If, however, the travelling wheels, turnable around their vertical axis, get under the plastic cover of the device base (3), then the brakes (14a) must be pressed (or released) manually.

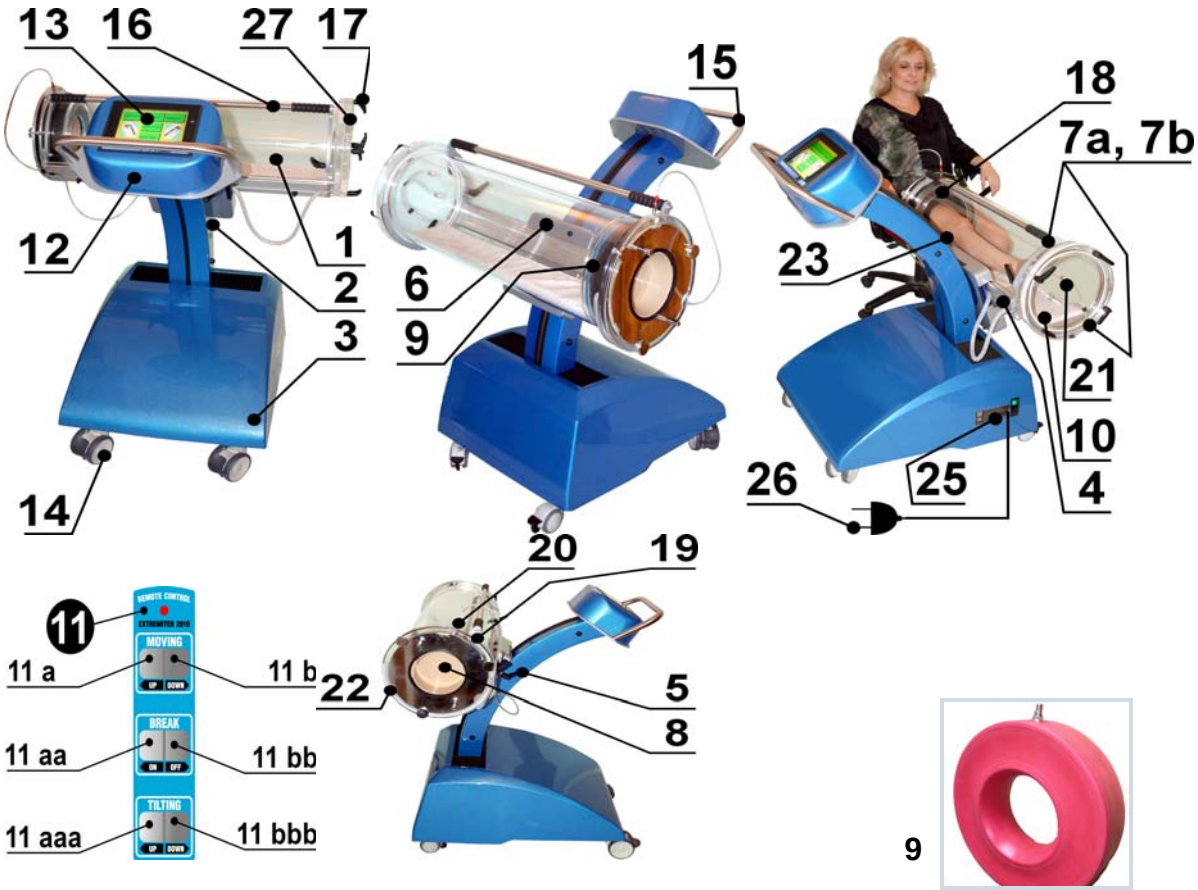
Good manoeuvrability with the device, possibility of a remote-controlled, motor-driven feed of the application cylinder (1) along the „shark fin“ type supporting arch (2) within a wide range of roll out and roll in of the application cylinder (1) upon the treated extremity up to 650 mm, as well as the remote control of motor-driven tilting of the cylinder allow positioning of the application cylinder (1) on the laying, sitting, and half-sitting patient. Usually, procedures are administered in sitting or half-sitting position. An integral part of the device is the application position chair (28). The successfully treating VCT procedure demands to use the special application position chair. Common chairs are not suitable. The chair is sufficiently robust, so it enables also the treatment for pacient with hight weight and with lowered moveability.

After the unlocking the brake is possible to move with the pacient to the left or to the right and by this way find the most optimal position for the administration of the procedure. In case of need is possible to take down the arm rest, this is very favourable for the immobile pacient. By this the ballast on the hip joint will be reduced.

The back stretcher reclines the head of the pacient and it is possible to tilt it to the supination position.

For VCT operation is necessary with minimal strangulation, perfectly hermetically seal treated extremity in the cylindric applicator of the device. For this reason new sealing cuffs from fuly biocompatibile natural rubber and hygiencically unexceptionable CIBA pigment was developped. This sealing cuff have higher elasticity of the sides, so treated extremity is not so much compressed. For all standard extremities of the patients with diverse construction, 6 sizes suffice(XS, S, M, L, XL, XXL). In between sealing cuff and patients extremity, the neoprene inlay, which further increasees the sealing pressure to the extremity and helps to optimalize the procedure, can be sling. These inlays are made in the set of 12 sizes.

For the operative and effective working is necessary to have a stand for the material. This stand was very properly developed like a essential but and needed part of the system for VCT administration.
The stand is made from easily desinfectioned and attractive stainless steel. The stand occupies minimally space hereat provides the pssibility of well arranged sealing cuffs and annulus positioning, at first hand reach of the physiotherapeutists.



9

28

28C

29

30

28A

Fig. 3.1 General view of the EXTREMITER 2010, „BETTER FUTURE“ edition, and description of the main parts of the device assembly.

Legend:

1. Hyperbaric / hypobaric application cylinder
2. Vertical supporting arch of a “shark fin” type
3. Device base
4. Separate linear guide (travel) and horizontal beam (cross member) of the application cylinder
5. „Dual“ type handle intended for locking the separate linear guide – horizontal movement of the application cylinder
6. Mechanical turn mechanism intended for tilting of the application cylinder (1)
7. Arms

    7a Supporting arms
    7b Closing arms

8. Neck of the application cylinder (1)
9. Inflatable sealing cuff
10. Removable bottom of the application cylinder (1)
11. Remote control of travels and positioning of the application cylinder (1): Motor-driven height adjustment of the application cylinder (1), tilt of the application cylinder (1), and brake application / brake release of the supporting arch movement (2)

    11a Motor-driven feed of the application cylinder (1) along the supporting arch (2) in the upward (UP) direction
    11b Motor-driven feed of the application cylinder (1) along the supporting arch (2) in the downward (DOWN) direction
    11aa Movement of the supporting arch (2) - brake released (ON)
    11bb Movement of the supporting arch (2) - brake released (OFF)

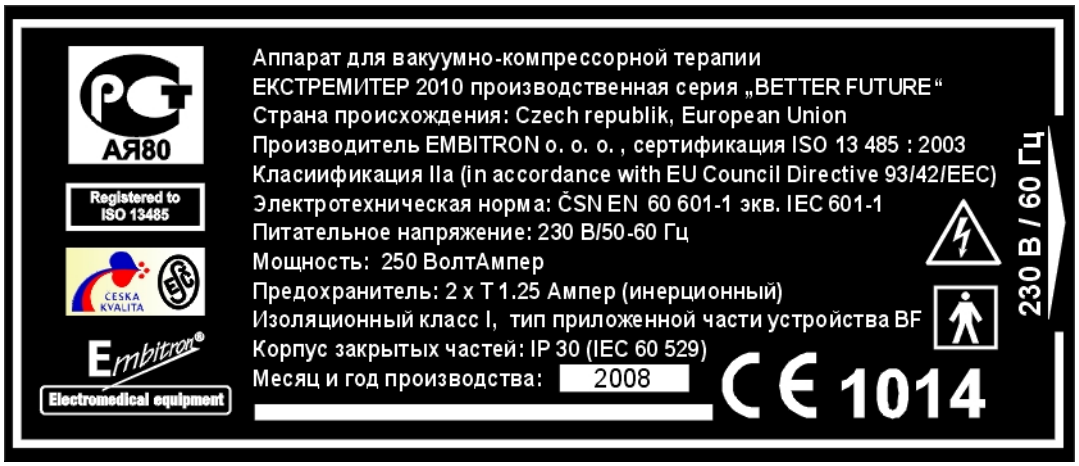
    11aaa Motor-driven tilting of the application cylinder neck (1) in the upward direction (UP)
    11bbb Motor-driven tilting of the application cylinder neck (1) in the downward direction (DOWN)

12. Control computer box with a control and display unit (control computer)
13. Touch screen of the control and actuating computer
14. Travelling wheels with freely turnable horizontal pins and brakes (14a)
15. Supporting arch travel holder (2), resp. entire device travel, also used as arm rest when working with the touch screen
16. Application cylinder travel holder (1) in the direction of cylinder axis, also used for lifting off the closing arms (7b) after release of the fixation handles (24a, 24b) in removal of the cylinder (1)
17. Fixation handles (4 pcs) used for release and removal of the application cylinder bottom (1), resp. its re-fixing and sealing
18. Internal supporting removable circular rings used for fixation of the sealing cuff (9) in the neck (8) of the application cylinder (1) from application area. The assembly consists of 4 pieces with internal diameters of 12 cm, 14.5 (15) cm, 18 cm, and 21 cm
19. External closing removable circular rings used for fixation of the sealing cuff (9) in the neck (8) of the application cylinder (1), placed on the edge of the cylinder (1) towards the patient, and secured by turning. The assembly consists of 4 pieces with internal diameters of 12 cm, 14.5 (15) cm, 18 cm, and 21 cm
20. Insertion piece of cuff pressurization
21. Insertion pieces of hoses and incoming pneumatic connector of pressurization (21a) / vacuum application (21b) of the application cylinder (1)
22. Circular pegs (3 pcs) located at the periphery of the application cylinder neck (1), on which the external removable circular rings (19) are to be placed, secured by turning
23. Stops of linear travel of the application cylinder (1) in the direction of its axis: To the right (23a), to the left (23b)

24. Fixing handles of arms (24a to the right, 24b to the left); after their release by means of the holder (16), the closing arms (7b) can be tilted off, and, after releasing the hoses, the a application cylinder (1) can be removed
25. Appliance inlet of electric power supply, intended for insertion of mains supply plug connector network – the cord (26). In the cord block, there is a power supply switch, 2 fuses T 1.25 A, as well as device label near the cord
26. Detachable mains supply - mains cord
27. Sealing of the application cylinder bottom (“o” rings)
28. Application position chair with removable sides and possibility of moving of the pacient left/right
29. neoprene inlay, intended for putting between the pacient´s extremity and the sealing cuff
30. Stand for the material of VCT

All functional components of the Extremiter device 2010 Better Future edition are placed on the “robust” construction made from exact laser thick-walled iron-plate slops, which are connected by welding and screwing. Some of the exact parts are sharpened. Complicated components are tooled by paring and turning on modern CNC machines. There is used bearings with long lifetime. Plastic function parts are made from highly abrasion resistance plastics, for example the type Murtfeld. Metalic inside parts are provided by colour adjustment – komaxtit. The parts which can´t be adjust by this way are external zinced, chromed or it is used by stainless steel. Because of using of these technologies, the lifetime, the reliabilty and the construction maturity of the device are maximal.

3.2 Legends on the Device



Device name	EXTREMITER 2010	
Manufacturing edition	„BETTER FUTURE“ edition	
Manufacturer’s name	EMBITRON s.r.o.	Borska 55, Plzen, 301 00
Manufacturer’s certification		ISO 13 485 : 2003
Country of origin		Czech Republic European Union
Electrotechnical classification		Insulation class I
Health classification		II a (in accordance with the EU Council Directive 93/42/EEC)
Electrotechnical standard used		CSN EN 60 601 – 1 eq. IEC 601 – 1
Determined power supply voltage		230 V / 50 Hz –60 Hz
Electric input		220 W
Enclosure of encapsulated parts		IP 20 (IEC 60 529)
Type of applied part of device		BF (CSN EN 60 601 – 1 eq. IEC 601 – 1)
Year of manufacture		
Serial number		
Warning		The device is able to produce the positive pressure up to +25 kPa and negative pressure up to -25 kPa
Fuses at electrical input of power supply		2 x T 1.6 A , L 250 V
Obligatory reference to the Product Documentation		
Temperature range: operation / storage		10°C – 40°C / 5°C – 50°C
Maximum humidity: operation / storage		75% / 75%

4 Operation of the Device EXTREMITER 2010, „BETTER FUTURE“ Edition

4.1 Installation of the Device and Testing its Mechanical Parts

The device EXTREMITER 2010, „BETTER FUTURE“ edition, is installed in a simply way. However, the device should be installed by a qualified expert, trained and authorized by the manufacturer.

If the device was delivered in a transport case, side walls and top wall of the case must be removed first. The procedure for taking the device out of the transport case is illustrated with pictures located directly on the case.

In doing so, the shipping case must not be opened using excessive force. Removable walls and top wall are bolted and the bolts must be unscrewed – preferably, using a cordless screwdriver. Then, the device assembly is to be gradually taken out, and individual components are to be carefully unpacked. First, smaller and lighter parts are taken out, such as sealing cuffs (9), supporting (18) and closing (19)

circular rings, remote control of travels and positioning of cylinder (11), mains supply (26), accompanying documentation, and the like. Particular attention is be given to taking out the application cylinder (1) and its unpacking, because this is a very fragile item. Some parts, such as the application cylinder (1), are not only closely packed, but they are also within the transportation case firmly fixed using contracting bands that must be released. These bands are usually released using double safety locks on their metal connecting carbine hooks. The bands are not cut so that they can be reused if the device must be uninstalled and safely packed for any other transport. Finally, the transport case will contain a basic component of the device, consisting of the base (3) with the vertical arch (2), computer box (12), and the horizontal cross member of linear travel (4). The basic device component is thoroughly fixed by contracting bands, and the device base is firmly linked to the bottom of the case. These connections must also be released by unscrewing the bolts. The released base component will be taken out of the transport case and put on the travelling wheels (14).

In handling and lifting the device, use withdrawable holders (30) - two holders in front and two holders in back. For handling and lifting, never use edges of plastic covers, arch (2), control computer (12), and the like. The holder near the control computer box (15) is used only to keep balance during manual transport. The withdrawable holders (30) can be provided with rubber protection to facilitate manual transport.

Caution: After installing the device, the withdrawable holders (30) must be placed under the device base.

Further, all protective transport packages must be removed. Then, release the arm fixation handles (24a, 24b) and lift off the closing arms (7b) by pulling the holder (16). The application cylinder (1) is to be placed into a created area in such a way that the bottom of the application cylinder is directed towards the side of the base (3) with incoming mains cord (25). The application cylinder must sit down on silent blocks of the supporting arms (7a). Then, the closing arms (7b) are to be put on the application cylinder (1) using the holder (16), and silent block of closing arms (7b) are to be firmly pressed on the application cylinder (1). In this position, the arm fixation handles (24a, 24b) are to be firmly tightened. The fixation handles 24a, 24b are placed with threads in the opposite direction, therefore, the direction of tightening / releasing is contrary.

Caution: All fixation „Dual“ type handles enable usual tightening or releasing or idle rotation with the handle. This idle rotation of handle can be achieved by lifting up the handle in the direction of bolt axis at concurrent pressing (holding) the upper part of the handle.

Further, check tightening and, if necessary, tighten the fixation handle (5) intended for locking the linear travel of the application cylinder (1) in the direction of its axis to prevent spontaneous travel of the application cylinder (1) when the cylinder is tilted in linear displacement. Adequate and uniform tightening of all four handles (17), fixing and sealing the bottom (27) of the application (1), should also be checked. Connect the insertion pieces of hoses (21a, 21b) to the cylinder bottom (27) for pressurization and vacuum application of the application cylinder (1). These insertion pieces can mutually be located arbitrarily. The insertion pieces of hoses are designed as quick-release connectors, which means that connection can be made by mere insertion of insertion pieces into openings of the pneumatic connector on the bottom of the cylinder (27), and disconnection is made by pulling out the insertion piece in the direction of axis of the pneumatic connector at concurrent pressing the ring at the connector nose in the opposite direction – towards the bottom of the cylinder (27). On the linear travel (4), check the presence of both distance stops of travel (23a, 23b). Check also whether the main power switch, located in the cord block (25), is switched off. Once you check the safety and suitability of electrical installation according to valid local standards in the area where the device is to be installed, you can connect the plug connector of mains supply to appliance inlet of the device (25) and insert the mains supply to the outlet of electrical installation. If the local electrical distribution network uses other types of sockets that are used in the Czech Republic, consult this situation with a qualified electrician who is responsible for use of adapters or installation of other types of connectors. In the case of local electricity networks of another type of protection against dangerous line voltage, it is necessary to ask for the opinion of local skilled and responsible authority. The power supply voltage and line frequency must be strictly observed.

Caution: Any intervention must not affect the electrical classification of insulation safety of device - Class I.

Caution: Read the device labels and study carefully the instruction manual (Accompanying User's Documentation).

Caution: If the device is brought into a warm room from the outside cold environment, it may be misted with condensed water vapours. The device can be connected to the electricity network, and switched on, only if it is completely dry.

Note: If the device must be transported, for example, to a place with a narrow door, the horizontal beam (4) must be removed. In removed application cylinder (1), take off one of the stops (23a, 23b) of linear travel. Then, on the same side, unscrew two bolts at the edge of linear feed – horizontal beam (4), fixing the supporting arm (7a). In doing so, the fixation handles (24a, 24b) of arm must be firmly tightened to avoid collapsing the closing arms (7b) and connecting holder (16). Slightly take away the released arm from the edge of horizontal beam (4) and go out of rollers with the entire linear travel.

Caution: The beam (4) and arms are relative heavy.

Reassembly should be done in a reverse manner.

After meeting all appropriate conditions for the safe operation of electrical network devices in medical premises, the Extremiter can be connected to a relevant electricity network, BUT only through the UPS – Uninterruptible power supply - and the main switch (block 25) can be switched on. Leave the device switched on for a few minutes and monitor its behaviour. You should hear only a quiet sound of cooling fans. On the monitor (touch screen) of the device (13), monitor the start of computer and application control software. Neither atypical sounds should be heard, nor unusual odour felt. If the device does not start after switching on, protective blow-out fuses located in the cord block (25) will probably be damaged. Replace these fuses with the provided fuses of a same type and value (T 1.25 A). The fuse case can be opened by its turning with a tool inserted in an accessible groove of the case.

Caution: If you need to replace fuses, the device must be turned off and, mandatory, disconnected from the electric distribution network.

During the start-up of the device, you can prepare a remote control (11). Open the remote control case in a marked place and insert a miniature power supply battery of A23S type, 12 V. Check whether the application cylinder (1) moves in a safety area and, using the remote control, check the travel (MOVING) along the vertical supporting arch (2) UP and DOWN, as well as tilting the application cylinder (TILTING) to one side and other side (UP, DOWN), as well as brake release of the entire vertical arch (BRAKE – ON), its manual transfer to the right and left extreme positions, and brake release (BRAKE OFF). During manual travel with the entire vertical arch, you must check whether the arch is released. When moving with the cylinder (1), use the holder (16) preferably.

Caution: Neither lift the holder (16) upwards, nor tilt it in the direction of closing arms (7b), as this will result in forcible extraction of arm fixation handle (24a, 24b).

If all these checked functions of application cylinder (1) positioning work fully reliably, you can also check the manual feed of the application cylinder (1) using a linear horizontal travel (4) in the direction of the cylinder axis. In doing so, hold the cylinder holder (16) and travel very carefully to prevent from damage the air supply hoses leading to the cylinder bottom (27) and cylinder neck (8), as well as prevent from hitting the stops of linear horizontal travel (23a, 23b). Manual travel of the application cylinder (1) by means of the linear horizontal travel (4) should also be checked at the tilted cylinder. In this case, however, you must firmly hold the cylinder to prevent from abrupt run off the cylinder, along the tilted linear travel. As well as, you can check superposition of cylinder feed (1) in the direction of its axis, both by feed of linear horizontal travel (4), and by manual travel of the entire, brake released shark fin type vertical supporting arch (2). Check also complete roll out of the application cylinder (1) from the patient and, subsequently, complete roll in of the application cylinder (1) towards the patient (in order to slide the application cylinder over the patient's unbent extremity). The patient is always located in the vicinity of the application cylinder neck (1), i.e. on the opposite side of the appliance inlet of electric power supply (25). The above specified handling should be checked both in the lower position of the application cylinder (1), where lower extremities will typically be treated, as well as in

the upper position of the application cylinder, where upper extremities will be usually treated, as well as in the middle position, which correspond to treatment of a patient sitting on a high bed or couch. Handling should be checked at the horizontally placed cylinder, as well as at variously tilted cylinder. Manual and motor-driven travels must go fluently and smoothly.

If an original chair is part of the delivery, test its travel on travelling wheels, as well as brake application / brake release of these wheels.

Also test the travel with the entire device and brake release / brake application of relevant travelling wheels.

If you already managed the technique of travel with the entire device and chair, and positioning of the application cylinder (1) you can proceed to opening and hermetic closing the cylinder. After unscrewing and removing four fixation handles (17), remove the cylinder bottom (27). Draw the bottom out carefully in the direction of cylinder axis. If the insertion pieces of hoses (21a, 21b) remain connected, place the cylinder bottom (27) in such a way to prevent from damage of these hoses. The opened bottom will enable to clean and disinfect perfectly the internal area of the application cylinder (1), or to handle the distal part of the patient's extremity during insertion of the extremity into the application cylinder (1), padding the extremity, or placing various diagnostic sensors of biologic magnitudes on the treated extremity. During reclosing the cylinder bottom (27), first you must check for the integrity of circular sealing and its uniform and perfect insertion in a particular groove. If these requirements are not met, position of silicone sealing must be adjusted, or this sealing must be replaced. The cylinder bottom (27) is to be attached to the cylinder in the direction of cylinder axis (1) and carefully screwed using four fixation handles (17). The handles are to be uniformly and adequately tightened. Circular sealing must sit down uniquely along the periphery. Do not use excessive tightening force. If necessary, the handles can also be tightened under operation.

During transport and demonstration operation, the neck (8) of the application cylinder (1) is provided with an inflatable sealing cuff (9) with the opening of 16 cm in diameter, sealed with a gland fixed in the neck (8) from both sides with supporting (18) and closing (19) circular rings with internal diameters of 14.5 (15) cm or 12 cm Only for the testing and demonstration purposes, the internal diameter of circular rings is lower than the internal diameter of sealing cuff (9).

Caution: For treatment of patients, however, the internal diameter of supporting (18) and closing (19) circular rings must be higher than the diameter of sealing cuff (9). The optimum difference of diameters should be 2 – 3 cm.

Caution: The extremity may be in contact only with the sealing inflatable cuff (9), not with the supporting (18) and closing (19) circular rings. This can be achieved by combination of cuff and circular rings of appropriate diameters, as well as optimal positioning of the application cylinder (1), specifically by adjusting the optimum height of the application cylinder (1) and, in particular, by fine tuning of its slope.

In addition, it is necessary to ensure that the patient's extremity is not directed crossways to the cylinder axis when he/she sits in the application chair. While the "crossway" location of extremity in vertical level is compensated by setting a suitable height and slope of the application cylinder (1), the "crossway" location of extremity in horizontal level can be compensated only by side travel or turning the application armchair on its travelling wheels. Naturally, it is possible to used side travel or turning the entire device (wheel brakes must be released). Released brakes of the device wheels and application armchair must be applied firmly again. If so allowed by the situation, the patient can slightly change its sitting position in the armchair, however, its final position must be fully comfortable and firm.

Caution: It is important to use the special application position chairs.

Caution: The sealing cuff (9) must fit uniformly and tightly enough around the extremity. Therefore, a sufficient amount of sealing cuffs with all necessary internal diameters must be available. The cuffs with the following internal diameters are used: XS, S, M, L, XL, XXL.. The sealing cuff (9) must tightly enough fit with its cylindrical area around the inserted treated extremity, however, the extremity must not be constricted.

Caution: Some leakages between the cuff and extremity can be compensated by a neoprene ring, which is to be put over the extremity, and it will fill a space between the extremity and somewhat larger

opening in the cuff. The neoprene rings are available in the wall thickness of 0.5 cm. They can be mutually threaded (stacked up) and you can achieve a higher wall thickness of built-up neoprene ring. Use of neoprene rings is suitable also in patients with increased sensitivity to pressure of inflated sealing cuff around the extremity.

Neoprene rings, however, cannot replace inflatable sealing cuffs of necessary internal diameters.

Let us go back to the demonstration and testing assembly in the cylinder neck. At this moment, we will not disassembly it, but it will be used for the pressurization / vacuum application test of the application cylinder (1). Insert the insertion piece of cuff pressurization (20) into the orifice of sealing cuff, coming through the opening in the cylinder neck (8), and secured by a screw nut. Connection is secured by the cone, therefore, the hose with the insertion piece should be only put into the orifice of the sealing cuff, and slightly pressed down. This solution is not only very quick in real situations, but also enables, at any time during the therapeutic procedure, if necessary, to complete pressure / vacuum action on the patient's extremity only by a slight withdrawal of the hose insertion piece from the cuff orifice.

Caution – very important:

While any manipulation with the device, especially at tilting and following covering of the holder (16) of the app.cylinder, it is necessary to watch out, that the hose of the air supply will be not damaged. This hose is important for measuring of the pressure in the sealing cuff, in case it will be damaged, than will be necessary a difficult repair.

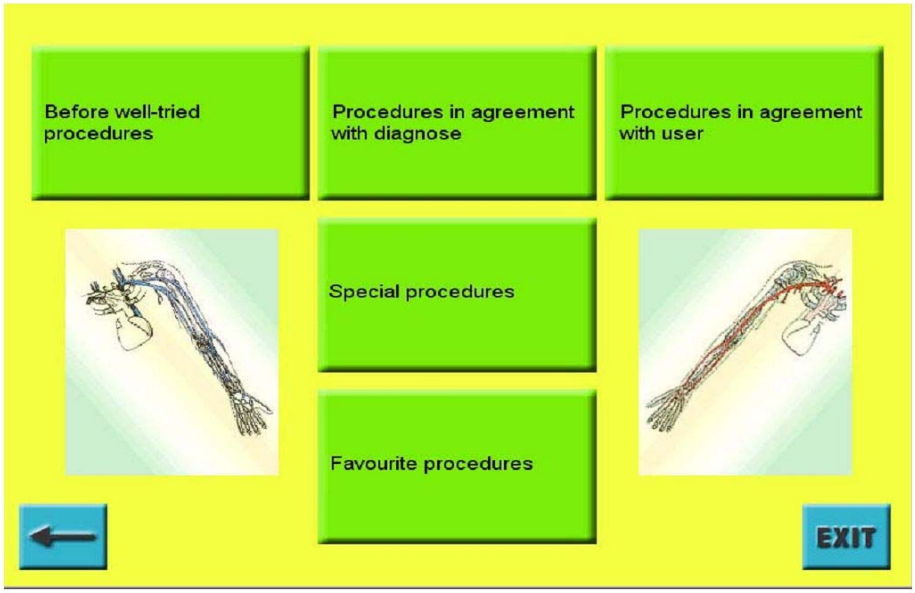
Also it is very necessary to watch out, that the measuring capillary, which goes through the compression hoses of the sealing cuff, has to be pushed out from the end of this hose. Together it should be put into the tyre valve of the sealing cuff as deep as it is possible

Other attention is to be paid to control from the touch screen (13) of the control computer (12).

4.2 Administration of Vacuum-Compression Therapy Procedures by Means of Control Computer

4.2.1 Introduction

The basic menu of device will display on the monitor. Check the language on this display. To change the language press the **LEFT ARROW BUTTON.**



Then, the language selection menu will appear:

To select a required language, touch a particular flag. If you cannot find your language in this set of flags, you can touch the globe icon to display other flags.

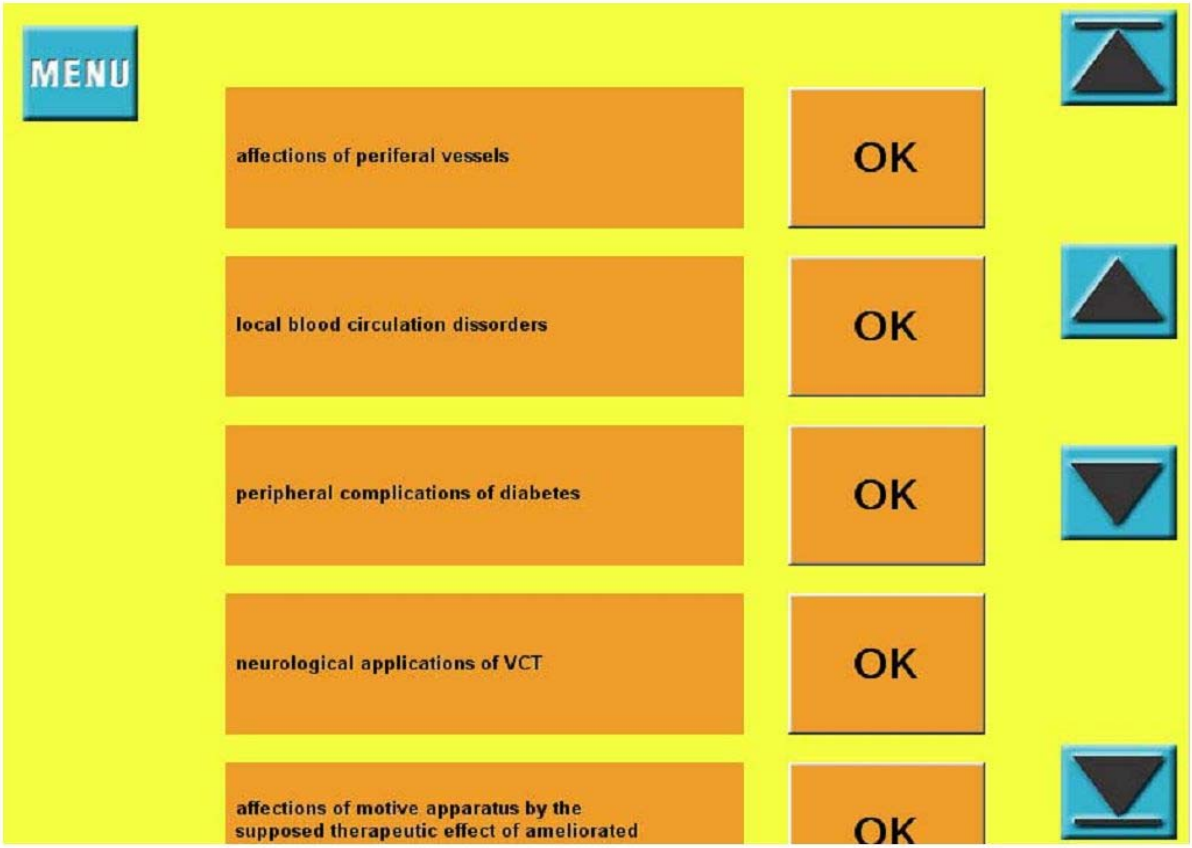
Caution: The provided devices are usually equipped only with a limited number of language options, whose utilization is expected at a place of installation.

In the above menu, you can also switch on or switch off an audible alarm of the device (the bottom at the left lower part of the display). The basic menu is usually accessed by selection of a required language.

The basic menu also enables the standard exit of application software, namely by pressing the **EXIT** button. After this action, you will get into the basic status of computer that can be switched off similarly as a regular PC (sequence of the **START** and **SHUT DOWN** buttons).

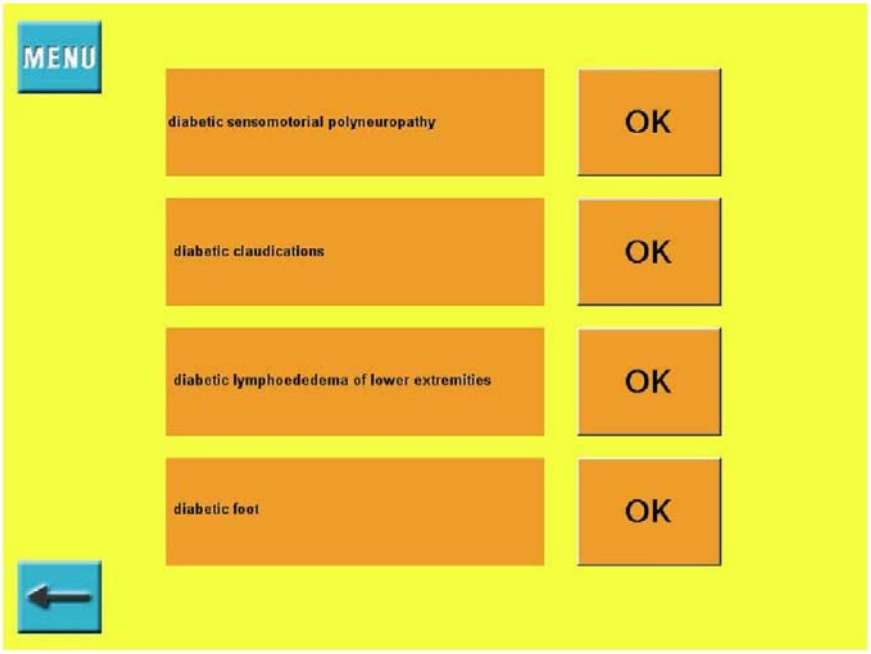
4.2.2 Procedures According to Diagnoses

From the basic menu, you can usually proceed further and select a particular group – a procedure folder: **„Procedures According to Diagnoses“**, **„Well-Proven Procedures“**, **„Procedures According to Users“, „Favourite Procedures“**. In case we are using the additional equipment of the device – the PC supervision, you can also use the folder “***Prescription”***.Is very probable that the **„Procedures According to Diagnoses“** will be your most frequent option**:**

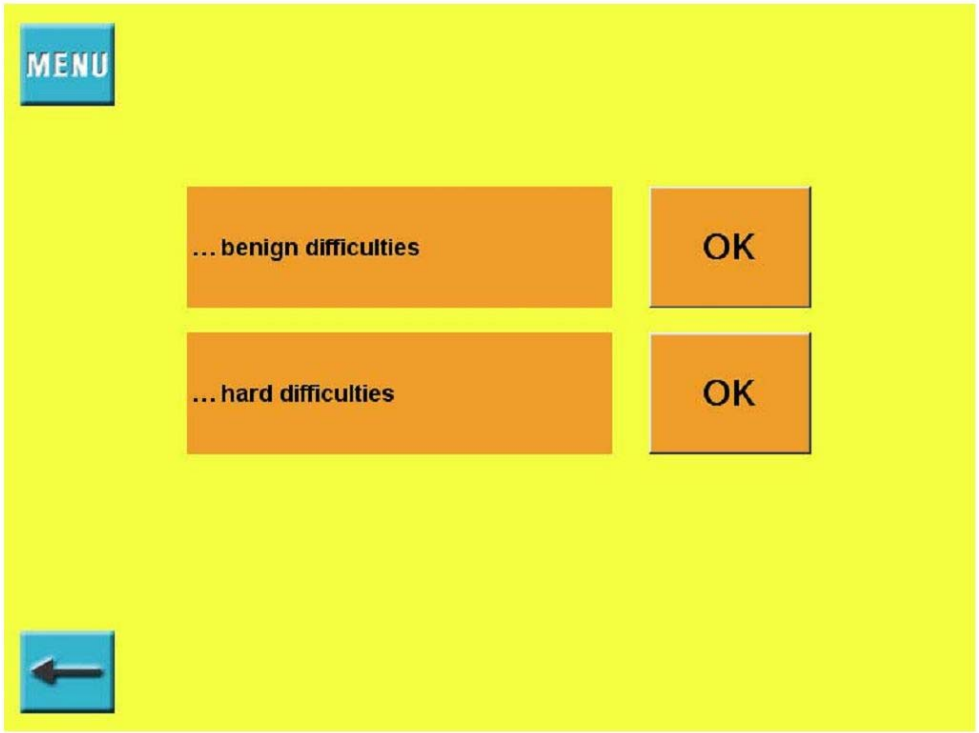


Here, the patient's disease is to be entered more specifically in gradual hierarchic options. To confirm your selection, press the **OK** button on the right, next to specification. In selection from more extensive lists, individual specifications are achieved by pressing the **up arrow up** or **down arrow** buttons, or you can move to the beginning of this list by entering one relevant hierarchic level, or you can move to the end of this list. For this purpose, you can use usual buttons – the highlighted up arrow / down arrow buttons. In selection of some diagnoses, there will be a higher number of hierarchic, finer and finer selection levels. You can return one step back at any time, or you can go back to the basic menu (the **MENU button**).

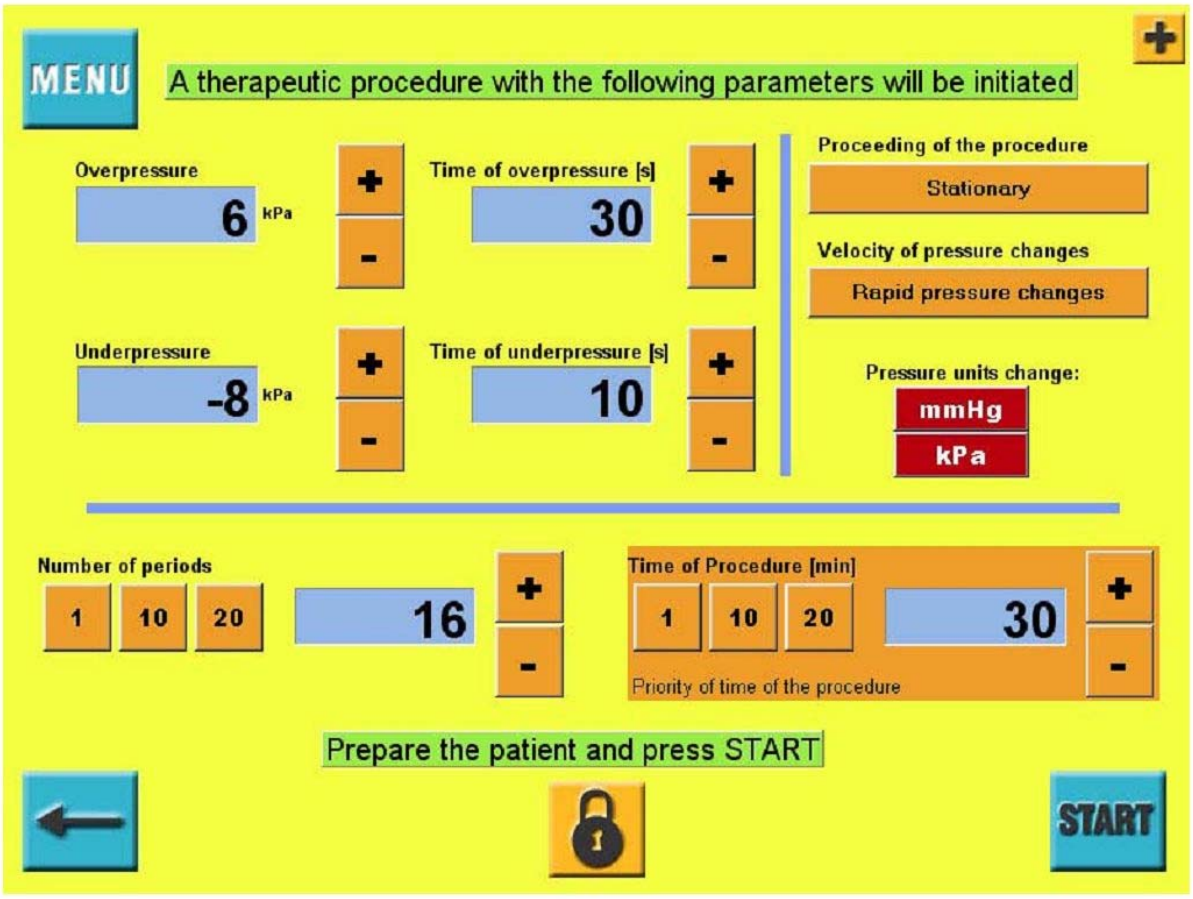
To illustrate this, use the following example for the selection of "Peripheral Diabetic Complications". Other level of hierarchic selection will appear. You will treat, for example, „Diabetic Sensomotoric Neuropathy",



more severe condition:

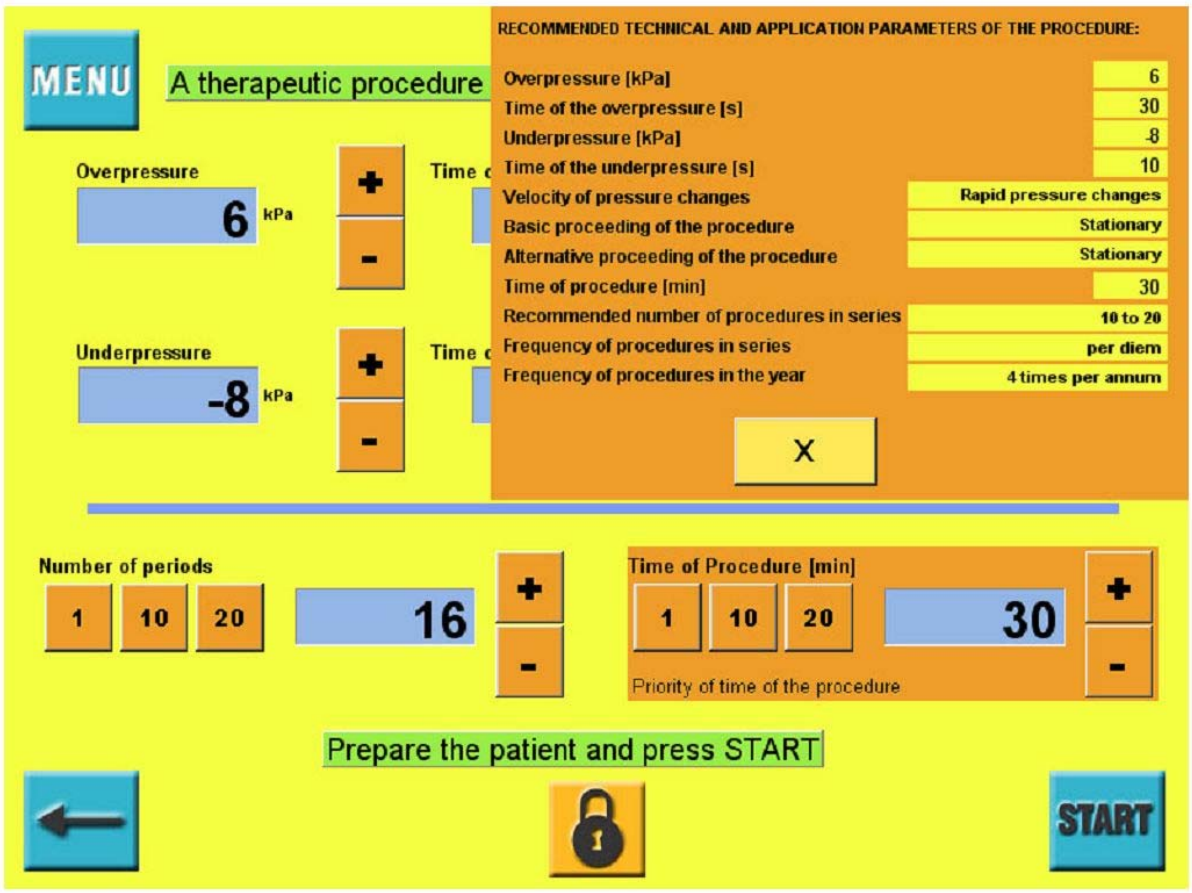


A selection of biotropic parameters of appropriate therapeutic procedure will appear (a so-called „pre-start condition“),



where you can choose to show pressures in kPa or in mmHg (see the buttons marked **mmHg** or **kPa**). All proposed therapeutic biophysical parameters can also be modified (see next).

By pressing the **+** button in the upper right corner of the display you can display technical and application parameters of a selected procedure, including the recommended number of procedures in series, therapeutic series in a year, and the like.



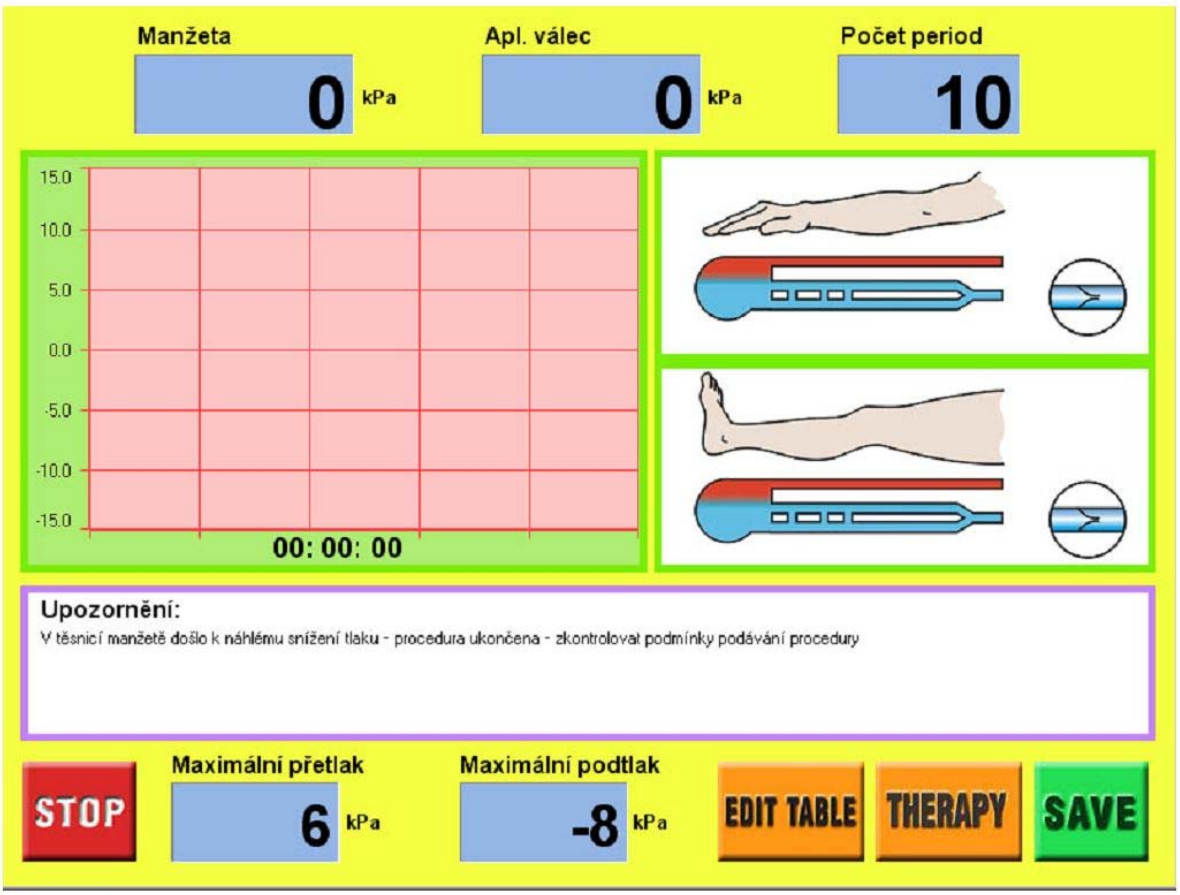
Caution: Even if the parameters of pre-programmed procedure are modified, the recommended technical and application parameters will remain unchanged.

If you accept the parameters of pre-programmed procedure, simply press the **START** button. If you do so, the therapeutic procedure will be started.

If necessary, however, you can modify the pre-programmed parameters. For this purpose, first you must press and hold down the button with a lock symbol:

Unlocking this imaginary lock will allow you to modify the parameters of the procedure:
For example, a 30 minute procedure, involving approximately 16 vacuum-compression cycles (periods), will be modified to a procedure with a firmly selected 10 cycles (periods), which will take about 18 minutes:

By pressing the **START** button, you will initiate the procedure:



In case we are using the control SW, which is intended to other additional possibilities - the start will be little complicated:

After the setting up of the procedure parametres and after the pressing START button, you will be questioned to the measuring of the starting position of the treated extremity. You will confirm it by the OK button. By the press of the OK button the process will be started. This last cca 15 seconds and the time of this process is visualized. After this is possible to press the START button again. The process has to find out the starting volume of the extremity, than will be possible to measure while administration of VCT procedure the changes of this volume.

In case we want not or we could not measure the extremity volume while administration of VCT, it is possible to pass the process, you will press the START button, after not the OK button, but again the START button and the VCT procedure is starting.

In case you need to realize the modification of parametres, you have to press and hold long the button with the symbol “lock”.

The unlocking enables to modificate the parametres of the procedure.
For example the 30 minutes procedure, which contains 16 vacuum-compression cycles (periods) we will changed the procedure to 10 cycles (periods), which will take cca 18 minutes.

By the press of the START button we will start the procedure.

In the upper part of the display (monitor), there are displayed four numerals, gradually from left to right they mean: pressure in the sealing cuff (9), pressure in the therapeutic application cylinder (1), number of cycles – periods (during the procedure, this time is decremented) and procedure duration (during the procedure, this time is incremented). The large green-framed area is intended to draw a graph of positive pressure and negative pressure course in the application cylinder (1), depending on the time of the current procedure. The propagation time of procedure is shown under the dynamically changing graph.

Depending on the pressure units selected in the previous menu ("pre- start" table), the value of pressure is displayed in kPa or mmHg.

To the right from the graph, there are two pictures, representing the upper and lower treated extremities with a schematic display of vascular bed, including the changing condition of venous valves. During the procedure, the pictures and diagrams are animated, depending on the alternation of negative-pressure and positive-pressure phases. In the positive-pressure phase, the extremity gets pale and reduces its volume because the venous blood is expelled. On the chart, this fact is reflected in reducing the volume of venous bed (blue) and narrowing the veins with a smaller flow of arterial blood into the extremity (red). In the negative pressure phase, fresh arterial blood (red) is suctioned into the extremity, the extremity changes its colour to red, but its volume is increased, including the volume of vein bed and dilatation of veins. These actions are cyclically repeated. Medically qualified operating personnel should be able, in accordance with the schematic diagrams, to observe these changes also directly on the patient's extremity, and depending on it, to modify the parameters of procedure.

Under the graphs and charts there is a zone, intended for listing and reporting errors, which may be generated by computer during the procedure.

Notice:

In context of this ability, the autodiagnostic subssystem monitors and controls all technical parametres during the procedure. In case any of these parametres want to exceed the limits, the user is informed about this immediately. Meantime the automatic tries to set up the tilted parameter. For example – the sealing cuff can´t not manage the appropriate pressure, so the device draws the attention and tries to pressurize it. So it is not an error yet. In case it is not possible to presurize the sealing cuff, the device report the error. And than it is necessary to look for the mistake. For example the user has to change the involved sealing cuff. In case a weighty error, the procedure will be stopped. It is possible to switch between the "reports".
It is necessary to consider, that the limits of watched parametres are sett up in control PC and it is possible to change them (SW SETUP of the device). It is also possible to create milder or stricter standards for work of automatic autodiagnostic subsystem of the device. These limits are from the producer so pre-sett up to satisfy all users. In case the user want to change these limits, it is kindly recommended to entrust the producer . It is possible to make this operation at a distance – via the remote technical managment by help of internet or on the signal GSM through GPRS modem. More in the User´s Manual of the additional arrangements of the device.

In the left bottom part of the display (monitor), there is a significantly **STOP** button intended to stop the running procedure. In addition, the blue fields show the maximum applied positive pressure and negative pressure. The button with the symbol of straddle truck, which opens the control of positioning of the app. Cylinder (1), its movement up (UP), down (DOWN), tilting on one side and on the second side and brake release.

It can be needed to decrease or increase the pressure during the procedure, or to change the parametres of the procedure. To this purpose there are two buttons on the bottom ledge: PRESSURE

MODIFY and TIME MODIFY. After opening of the mod. menu the process is clear. Attention: Actual procedure will be with original pressure and time parametres.

In terms of the option of PRESSURE MODIFY it can be ignored the individual increasing and decreasing of the over and underpressure and the user can go straight to the systematical edit. Table (EDIT TABLE). The sense of this table is following:

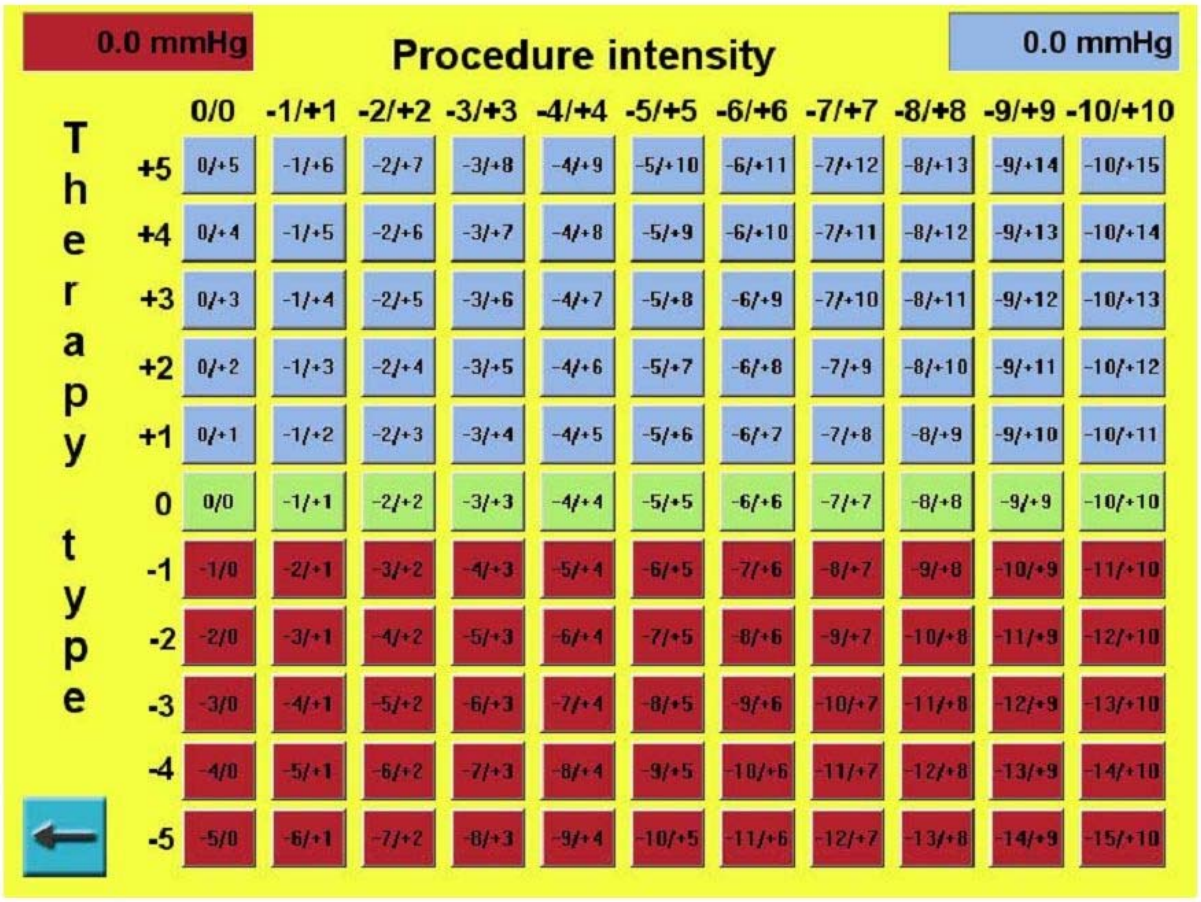
Each therapeutic VCT procedure has got an optimal combination of underpressure and overpressure. In case we would like to change the underpressure or overpressure parametres, we have to retain the effect of prevalent combination by incidence of both factors. For this purpose we can use the button EDIT TABLE. It is possible to use it there, where the combination of these factors will be retained, but the intensity is too high or to low and there, where we are not successfull – for example the extremity swells to much.

Let us show now, how to modify positive-pressure and negative-pressure values in the running procedure. Here, the main problem is that the procedure chosen from the folder "Procedures According to Diagnoses" (or from the folder "Well-Proven Procedures" and "Special Procedures") has established a certain optimal therapeutic combination of positive pressure and negative pressure. So, if you want to increase (or decrease) the intensity of procedure action during the procedure, you can not just change the positive pressure or negative pressure, but you must maintain a certain combination of action of both these factors, a so-called “direction” of treatment, or “sense” of treatment, or “orientation” of treatment. Further, let us consider that if you act only with symmetrical values of positive pressure and negative pressure (for example, + 5 kPa / - 5 kPa), you could talk about an increase in intensity of action if these values are increased. For example, intensity + 6 kPa / - 6 kPa is naturally greater than intensity + 5 kPa / - 5 kPa. The following table shows these intensities in the upper header of table columns. This approach will, however, not consider the fact that for the intended therapeutic action, we need a prevailing negative pressure sometimes (arterial problems, problems with perfusion, ischemia, cold extremities, etc.), and, in turn, sometimes we need a prevailing positive pressure (such as oedemas), and sometimes, only a mere equilibrium symmetry of positive pressure and negative pressure is a really optimal option. Therefore, a new variable called "Type of Treatment“ is established. This variable will characterize whether the predominance of positive pressure or negative pressure is required, as well as how strong this dominance should be. Negative values will reflect the predominance of negative pressure, and the more negative this value is, the more negative pressure will prevail over the positive pressure. Positive values will reflect the predominance of positive pressure, and the more positive this value is, the more positive pressure will prevail over the negative pressure. In fact, the term "Type of Treatment" is the number, which will be added to the value of positive pressure (if positive), or added to the value of negative pressure (if negative) at a selected intensity of procedure. By combination "intensity of procedure“ and "type of treatment" you will get a table with 121 fields, where each field represents a certain combination of positive pressure and negative pressure:

1. Typ léčby
2. Intenzita procedury

Komentář k typu léčby	Typ léčby vyjádřený stupněm +5 až -5	Intenzita procedury		0/0		1/-1		2/-2		3/-3		4/-4		5/-5		6/-6		7/-7		8/-8		9/-9		10/-10	
		Vzorec pro přetlak	Vzorec pro podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak	Přetlak	Podtlak
	stupeň	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa	kPa
V končetině je zapotřebí léčit především otok. Čím vyšší zvolíme stupeň (1 až 5), tím více budeme působit na otok, ale méně na dodávku kyslíku, žíly, metabolismus a trofiku končetiny	+5	v_plus +5	- v_minus	5	0	6	-1	7	-2	8	-3	9	-4	10	-5	11	-6	12	-7	13	-8	14	-9	15	-10
	+4	v_plus +4	- v_minus	4	0	5	-1	6	-2	7	-3	8	-4	9	-5	10	-6	11	-7	12	-8	13	-9	14	-10
	+3	v_plus +3	- v_minus	3	0	4	-1	5	-2	6	-3	7	-4	8	-5	9	-6	10	-7	11	-8	12	-9	13	-10
	+2	v_plus +2	- v_minus	2	0	3	-1	4	-2	5	-3	6	-4	7	-5	8	-6	9	-7	10	-8	11	-9	12	-10
	+1	v_plus +1	- v_minus	1	0	2	-1	3	-2	4	-3	5	-4	6	-5	7	-6	8	-7	9	-8	10	-9	11	-10
Při tomto typu léčby ideálně rovnovážně podporujeme metabolismus končetiny, avšak nejsme schopni s maximální účinností cíleně působit ani na převažující poruchy arteriálního prokrvení, ani na případný edém	0	v_plus	- v_minus	0	0	1	-1	2	-2	3	-3	4	-4	5	-5	6	-6	7	-7	8	-8	9	-9	10	-10
V končetině je zapotřebí léčit především nedostatečnou dodávku kyslíku, nedostatečné zásobování živinami a zhoršenou trofiku, čím nižší zvolíme stupeň (-1 až -5), tím více budeme působit, avšak s nízky nadměrného hromadění krve a lymfy v končetině, není-li jejich odtok plně fyziologicky	-1	v_plus	- v_minus 1	0	-1	1	-2	2	-3	3	-4	4	-5	5	-6	6	-7	7	-8	8	-9	9	-10	10	-11
	-2	v_plus	- v_minus 2	0	-2	1	-3	2	-4	3	-5	4	-6	5	-7	6	-8	7	-9	8	-10	9	-11	10	-12
	-3	v_plus	- v_minus 3	0	-3	1	-4	2	-5	3	-6	4	-7	5	-8	6	-9	7	-10	8	-11	9	-12	10	-13
	-4	v_plus	- v_minus 4	0	-4	1	-5	2	-6	3	-7	4	-8	5	-9	6	-10	7	-11	8	-12	9	-13	10	-14
	-5	v_plus	- v_minus 5	0	-5	1	-6	2	-7	3	-8	4	-9	5	-10	6	-11	7	-12	8	-13	9	-14	10	-15

The following table will appear on the display of the control computer:



The more you are right in the table, the greater intensity of therapy exists. The more you are on top, the more emphasis is given on the effect of positive pressure (influence mostly over veins – venous and lymphatic drainage), and the more you are on bottom, the more emphasis is given on the effect of negative pressure (influence mostly over arteries – inflow of fresh blood with oxygen and nutrients, or pharmaceuticals). In the middle horizontal row of the table (marked with the value of "type treatment" = 0), fully symmetrical values of positive / negative pressure are given. In terms of the established "type of treatment" parameter, the table is divided into three parts – strips: The upper strip, consisting of five top rows of the table (with row headers +1 to +5), is dedicated for pressure parameters of procedures with prevailing positive pressure – especially for the treatment of extremities with the presence of oedema, or risk of its occurrence. This part of the table is marked in blue, as it represents an area of pressure parameters which have an impact mainly on the venous system. The middle strip consists of a single row with header 0, and is dedicated for pressure parameters of the procedure with an ideal symmetry of positive / negative pressure action during each cycle of the procedure. For illustration, this is marked in green. The lower strip, consisting of lower five rows of the table (with row headers -1 to -5), is dedicated for pressure parameters of procedure with prevailing negative pressure – especially for the treatment of extremities with trophic disorders, perfusion disorders, ischemia, and the like. This part of the table is marked in red, as it represents an area of pressure parameters which have an impact mainly on the arterial system.

Caution: You should not move between the specified three parts of the table during modification of pressure parameters of procedure during the procedure.

And now, practical examples:

*If, after pressing the **EDIT TABLE** button you enter the table in order to modify pressure parameters of procedure, we must first find the appropriate field, relevant to the positive / negative pressure applied so far. In our case, this field is + 6 kPa / - 8 kPa. This field can be easily found when you realize that the combination + 6 kPa / - 8 kPa was created as a superposition of pressure intensity of procedure +6 / -6 and the „type of treatment"= - 2 (prevailing action of negative pressure over the positive pressure by 2 kPa). So, you have to look in a column with the heading +6 / -6 and in row with a value of -2. We can find that we are at the bottom part of the table - the bottom strip (prevailing negative pressure). For this bottom part of the table with prevailing negative pressure we can say that increase in power of action of procedure can be achieved after moving in a diagonal direction right down – in moving by one step, you will find yourselves at field -10 / +7 kPa. On the contrary, decrease in power of action of procedure can be achieved after moving in a diagonal direction to the left upwards – in moving by one step, you will find yourselves at field -6 / +5 kPa. These described movements are significant because the sense, orientation of therapeutic procedure given by combination of positive pressure and negative pressure will not be changed. From a particular field, however, you can move in other directions too: in movements horizontally to the right – to the left, you will maintain the "type of treatment," but you will change the intensity of action; in movements vertically upwards – downwards, you will maintain the intensity of action, but you will change the "type of treatment". In movements in the diagonally opposite direction (downwards to the left – upwards to the right), you will maintain the size of negative pressure and you will change only the size of positive pressure.*

On the contrary, for the upper part of the table with prevailing positive pressure over negative pressure we can say that an increase in power of action of procedure can be achieved after moving in a diagonal direction right up – in moving by one step, you will find yourselves, for example, from field +8 / -6 kPa on field +10 / -7 kPa. On the contrary, a decrease in power of action of procedure can be achieved after moving in a diagonal direction to the left downwards – in moving by one step, you will find yourselves, for example, from field +8 / -6 kPa on field +6 / -5 kPa. These described movements are significant because the sense, orientation of therapeutic procedure given by combination of positive pressure and negative pressure will not be changed. From a particular field, however, you can move in other directions too: in movements horizontally to the right – to the left, you will maintain the "type of treatment," but you will change the intensity of action; in movements vertically upwards – downwards, you will maintain the intensity of action, but you will change the "type of treatment". In movements in the diagonally opposite direction (downwards to the right – upwards to the left), you will maintain the size of positive pressure and you will change only the size of negative pressure.

In the middle row of the table, there is the "type of treatment" =0; the action of positive pressure and negative pressure is in absolute symmetry, and by movement along these fields of this row only the intensity of procedure can be changed.

The transition to a newly selected table filed with modified pressure parameters is practically made by long pressing (holding) the button made up of a selected field.

Caution: During this long pressing, new selected pressure parameters can be read at the top of the display in mmHg.

If the selected field is pressed and held for a certain amount of time, the running procedure will spontaneously change to newly selected values of positive / negative pressure. In our illustrative example, this regards the transition from values –8 kPa / + 6 kPa to values –6 kPa / +5 kPa:

There are two other buttons on the bottom ledge: THERAPY and SAVE.

The button THERAPY enables to verify during the procedure, which of the procedure is administrated. (see the following figure)

The button SAVE could be used after the end of the procedure. By the pushing of this button is possible to save the identification of the pacient, subjective and objective evaluation of the procedure. The datas are saved into the complete database of the pacients. The identificated procedure is possible to choose anytime from the folder: “Favourite Procedure”.

We confirm the requierement for the saving of the parametres.And to the marked stripes we write requiered datas. For the possibility of writing we open the helping keybord – we press the button KEYBORD.

We will confirm the written datas and go back to the running of the procedure.

Notice: For data writing is possible to use the external keybord also. There are USB ports for the connection of external keybord or mouse.

4.2.3 Favourite Procedures

All parameters of the running procedure can be saved (during the procedure) in the folder „**Favourite Procedures“.** To save these parameters, press the **SAVE** button.

Confirm the request for saving parameters of the running procedure and type the required data to one (or to all) from the marked strips. For this purpose, display an auxiliary keyboard by pressing the **KEYBOARD** button.

Confirm the entered data and return to an uninterrupted course of program.

Note:

Once the parameters of running procedure are saved in the folder **„Favourite Procedures“,** you can call up the saved procedure at any time. In the basic menu, press the button **„Favourite Procedures“.**

Decide whether in the database of your favourite procedures you will select according to the patient's name and surname, or identification number, or according to an arbitrary, previously established identifier. Confirm the selection by pressing the **OK** button. The below figure shows the result of selection according to the patient's name and surname:

If you do not remember precise wording of needed text, you can press the button **+** in the upper right corner of the display to call up a particular list in text format. In this list, search a particular text and enter it to required fields.

Then, you will get to a „pre-start" condition of selected procedure.

A particular procedure can also be called up by means of other, previously entered identifier. In the selection according to an „arbitrary identifier", such as diagnosis.Enter the identifier – in this example, a particular diagnosis.

Confirm this a get directly to the „pre-start" condition of selected procedure.

4.2.4 Well-Proven Procedures

From the basic menu by pressing the button „Well-Proven Procedures" you can proceed to this folder.

Here, you have exactly the same pre-programmed procedures, which were introduced, and by a long-standing practice extensively verified on the original production version of the Extremiter unit. These procedures are divided into three groups:

For prevailing arterial circulatory disorders and mostly arterial, respectively capillary conditional stagnation peripheral metabolism, and for related trophic disorders of extremities, improving the effectiveness of pharmaceuticals on the peripherals, etc., i.e. procedures with prevailing negative pressure over positive pressure - see the "red" fields of pressure parameters of the modification table EDIT TABLE.
For combined disorders with marked arterial and venous elements; also suitable for general reconditioning, regeneration, and rehabilitation purposes, i.e. procedures with an ideal balance of negative pressure and positive pressure - see the "green" fields of pressure parameters of the modification table EDIT TABLE.
For antioedematous use and prophylaxis of oedemas, i.e. the procedures with values of positive pressure over negative pressure - see the "blue" fields of pressure parameters of the modification table EDIT TABLE.

A particular group of procedures can be called up by pressing the **OK** button, for example, 1. from the given groups.

According to the „intensity" of its action, each group is divided into:

a group of procedures with a very mild intensity (3 procedures),
a group of procedure with a standard intensity (one procedure),
a group of procedures with radical intensities (3 procedures),
a group of procedures with extraordinary radical intensities (3 procedures).

The selected group of procedure(s) can be chosen by pressing the **OK** button, for example, selected „standard intensity“ (in this sense, the „total power of action“) will provide a well-proven therapeutic procedure with the following „pre-start“ table.

Then, the procedure can be started up, or modified. To “unlock“ the lock, press the button and hold it for a while and then, for example, you can reduce the value of negative pressure from – 8 kPa to – 7 kPa (by pressing the **+** button at a reduced value of negative pressure).

4.2.5 Procedures According to Users

The device EXTREMITER, „BETTER FUTURE“ edition, enables also to work with procedures whose all biophysical parameters are selected fully individually by the user. This regards the folder „Procedures According to Users“ which can be opened by pressing the relevant button.

Then, the screen of selections of all therapeutic parameters will appear, and it can be gradually filled out.

First, in the top row, select the intensity of procedure (+ / - symmetrical value of pressure / negative pressure), for example, +7 kPa / -7 kPa. Numeric values are immediately displayed in the relevant fields, and vertical stripes will appear on both sides of the display: The height of the right strip in blue (indicating exposure to the venous system) is proportional to the selected value of positive pressure. The height of the left strip in red (indicating exposure to the arterial system) is proportional to the selected value of negative pressure.

Then, in the second row on the device display, select the "type of treatment", such as: –4 kPa, which means that the applied negative pressure will be reduced by other 4 kPa, vacuum of –11 kPa will be applied:
:

In addition, you will select a so-called "Nature of Procedure". This is a parameter, which covers pressure parameters, the positive/negative pressure ratio, developing throughout one procedure - not just one cycle.

The CONSTANT nature of the procedure course means that in each cycle of the procedure, the value of maximum positive pressure (a so-called positive pressure plateau) and the value of the maximum negative pressure (a so-called negative pressure plateau) is still the same. If, for example, the procedure with the maximum positive pressure of 7 kPa and maximum negative pressure of -11 kPa is selected, these values will be achieved always (constantly) in each cycle. If, for example, 10 cycles (periods) will be administered in a procedure, the value of +7 kPa / -11 kPa will be achieved in each cycle.

If, however, the HARMONIZATION nature of procedure course is selected, it means that the first cycle of procedure will start with ideally symmetrical values of positive pressure and negative pressure of +7 kPa and –7kPa. The value of negative pressure will be, however, increased in each subsequent procedure, and precisely in the middle of procedure duration, i.e. in the 5th and 6th cycle, you will achieve the required limit values of +7 kPa / -11 kPa. Then, the value of negative pressure will be reduced in each subsequent procedure cycle, and in the last 10th cycle, the positive pressure and negative pressure will achieve symmetrical values, and the procedure will be completed with these values. This nature of the procedure is chosen if you want to achieve the predominance of negative pressure (or positive pressure) over the positive pressure (or over the negative pressure) given by the selected "type of treatment," but you want to achieve this in a very fine manner – gradually, and then, in a single procedure, you want to eliminate gradually, and again in a very fine manner, this asymmetry between the positive pressure and negative pressure. This is appropriate in patients, where the asymmetry of positive pressure / negative pressure is therapeutically required, but you want this action to come slowly during the procedure, and to slowly disappear at the end of the procedure.

The IMPACT nature of procedure course means that the first cycle of procedure will start with required asymmetrical pressure values, for example +7 kPa / -11 kPa, and this asymmetry is very slowly reduced in each next cycle of procedure, and in the last cycle of procedure, here for example the 10th cycle of procedure, you will end with ideally symmetrical values of positive pressure / negative pressure, i.e. +7 kPa and –7kPa. This means that the asymmetry effect of acting positive pressure / negative pressure is considerably eliminated at the end of procedure. This is appropriate in patients, where the asymmetry of positive pressure / negative pressure is therapeutically required, but you want this action to slowly disappear during the procedure. In this manner, for example, in patient with ischemia of extremity, treated with the prevalence of negative pressure of -11 kPa / 7 kPa, you will fight against the risk of development of oedema of the extremity, resulting from the "aspirated" arterial blood into the extremity, the patient may have be apt to.

The LASTING nature of procedure is opposed to the previous impact nature. This means that, in the first cycle of procedure, you will start with ideally symmetrical values of positive pressure / negative pressure (in our illustrative example: +7 kPa / -7 kPa), but asymmetry is very slowly increased in each other cycle of procedure in the direction of required “type of treatment”, and in the last cycle of procedure, here for example the 10th cycle of procedure, you will end with required asymmetrical pressure values, for example, +7 kPa / -11 kPa. This means that the asymmetry effect of acting positive pressure / negative pressure is marked at the end of procedure. This is appropriate in patients, where the asymmetry of positive pressure / negative pressure is therapeutically required, but you want this action to slowly appear during the procedure. In this manner, for example, in patient with ischemia of extremity, and, at the same time, very sensitive to a therapeutic under pressure action, you will try to achieve the best results of treatment at the most possible sensitive approach.

The COMPENSATED nature of procedure applies an impact nature in the first half of procedure, but in the second half of procedure, this nature is completely overturned (compensated) in the meantime acting asymmetry. In our illustrative example, the procedure is started in its 1st cycle with the values of +7 kPa / -11 kPa („type of treatment“ = -4). This asymmetry is reduced in each subsequent cycle, and precisely in the middle of procedure duration (in the 5th and 6th cycle), you will achieve the symmetrical values of +7 kPa / -7 kPa. Then, from the 7th cycle of procedure, the “type of treatment” will be changed and (in our illustrative example) you will act with the predominance of positive pressure, and, at the end of procedure, in the last cycle, you will end with the following values: positive pressure = +11 kPa, negative pressure = -7 kPa („type of treatment“ = +4). In this manner, you will proceed, for example, in a patient where you want in a single procedure to gradually combine effective action on the arterial and venous components of the vascular system of extremity, where you must effectively treat ischemia of extremity, but at the expense of oedema resulting from the grounds of insufficient drain of venous blood and lymph from the extremity. In the second half of this procedure, you will remove this stagnating venous blood, or lymph, also even at the cost of reduction of long-lasting therapeutic effect.

The UNCOMPENSATED nature of procedure is opposed to the previously described harmonization nature. The required asymmetry of therapeutic action of positive pressure / negative pressure is marked both at the beginning and at the end of procedure. In our case, in the 1st and the 10th cycle of procedure. Precisely in the middle of procedure duration, i.e. in the 5th, or the 6th cycle, the positive

pressure / negative pressure action is ideally symmetrical. This approach can be used when you are going to combine the impact and persisting natures within a single procedure.

In addition, it is necessary to select whether pressure changes between positive pressure and negative pressure (and vice versa) run as fast as possible, or whether you want them slow down purposely. The use of faster changes (see the following figure) is a more frequent approach. In some sensitive patients, or patients with a very reduced venous flow when any transfer of a certain volume of blood between the body centre and periphery is very slow, and, specifically, where low values of negative / positive pressure must be selected, you can advantageously use the deceleration of pressure changes.

After selection of all therapeutic biotropic parameters of "user" procedure, the "pre-start" page will appear, where you can carry out any corrections or modifications of selected parameters, or you can start the prepared procedure.

However, you have another possibility, namely to save into memory a relatively hard compiled "custom" procedure before its running.

Caution: This is a different type of saving than saving the procedure to the “Favourite Procedures” folder. Here, the procedure is saved only within the folder „User Procedures“ before the start of the procedure itself.

By pressing the **Save Procedure** button, you will call up the following option of saving where only one arbitrary identifier is used.

The compiled „user“ program with the parameters: negative pressure – 11 kPa / positive pressure + 7 kPa; positive pressure duration - 25 seconds, negative pressure duration - 15 seconds; nature of procedure - „impact“; pressure changes - „fast; 10 cycles are preferentially entered, which corresponds to the procedure duration of 21 minutes, will be saved with the identifier (name) „ischemia cum oedema intermitens“, and the procedure can be started.

If, at any time, you select “Procedures According to Users” in the basic menu, a menu intended for compilation of “user” procedure will appear, but it is not necessary to compile a particular procedure in a complicated manner, but pressing the **Load Procedure** button you will enter the database of saved user procedures:

Enter the identifier under which a particular user procedure was saved (if you forgot the precise name of this identifier, by pressing the **+** button you will call up all identifiers of saved „user“ procedures).

After confirming the selection, the “pre-start” page of searched “user” procedure will appear and you can start this page.

After starting this procedure, all parameters are saved in the procedure folder called „Procedures According to Users“, but, generally, you can consider this procedure as favourite, therefore, it can be saved also in the „Favourite Procedure“ folder. This can be done, of course, during the procedure, by pressing the **SAVE** button, after confirming the selection, save this “favourite” procedure, for example, under the name and surname of the patient.

If you select, at any time, the „Favourite Procedures“ folder in the basic menu, you will make a selection of identifier of particular type (here the patient’s name and surname), enter the name and surname searched (if the precise syntax is forgotten, use the **+** button in the upper right of the display

corner),and then, you can call up the “pre-start” page of required procedure without any problems and subsequently, you can start the procedure.

4.2.6 Prescription

From the supervising PC (the additional arrangement to the device Extremiter 2010 BF edition) is possible to make the prescription of the procedure for the pacients and these datas send directly to the device, where the staff can very easy without mistakes start the procedure. More you can find in the User´s Manual of the additional arrangement to the device Extremiter 2010 BF edition.

4.2.7 Termination of Control Software Running

During the procedure you can see the graph of actual pressurized values in application cylinder. It´s time axe is pre-set up for 5 minutes - the distance of the vertical lines of the grating always 1 minute. This standard gauge can be changed: after pressing on the appropriate button on the Touchscreen in right bottom corner of the graph it appears blue field, where is possible by the help of button +/- change the gauge. The change will be confirmed by the button OK. The field is closed by the button X.

4.2.8 Displacement of the Graph

By the button in the left bottom corner (goes turn red) is possible to move the graph at its determinate field.

Database

In context of transfering datas about the administrated medical procedures it was urgent to create a database. This database is a standard part SW equipment of the version 2 of the control computer. It serves as a significant super-structure, it supports the remote supervision of administrated procedures and treated pacients.

We will press the button on the bottom edge of the monitor to start the adequate database on the control computer.

The database rises by writting parametres after the procedure. Identificators are the datas about the pacients, the datas about the administrated procedure and its treating effects.

4.2.9 The operating of standard PC functions

A. Calibration of Touchscreen

It is necessary from time to time to carry out the calibration, which ensures, that the place of the touch responds exactly to the point on the flat. For this purpose the computer is equipped by a special calibration program, which you can start as follows:

Start/All Programs/PenMount Universal Driver/PenMount Control Panel. After the startup we click on the pictogram of the pencil – PenMount 6000 ISB and press the button Configure. Then we press the button Standart Calibration. After this we have to touch by the help of Stylus in some point of Touchscreen.

Caution:
After the calibration process we have to save this into the internal memory of the PC, we click on the pictogram COMMIT in OS Windows Embedded and after restart the PC and wait for the new application seizing.

B. Volume control

The Loundspeaker volume we can set up as following:
START/Control Panel/Sounds and Audio Device Properies
Then we choose the intensity of the voice: LOW – HIGH or we can switch off the voice (MUTE). The voice intensity we can control also as following:
START/All Programs/Accessories/Entertainment/Volume Control

C. Entry to the internal memory of the control computer by the order COMMIT

After all changes (parametres, calibration, volume control etc. is necessary to save all this into the internal memory of the control computer by the pictogram COMMIT, on the PC sheet in OS WiNDOWS EMBEDDED. After this is necessary to restart the computer (START/Shut Down – in the tab change to Restart, then OK and then wait until the new application seizing.

D. History of the procedures

It is possible thereby:
D:/Database/Data/HistProc.

E. Setting up off data and time of control PC

START/Control Panel/Data and Time.

F. The connection of the control PC to the Internet
In case we want to connect the PC to the Internet, first we have to connect the cabel LAN with the ending RJ 45 into the appropriate connector (on the tablet under the box of control PC or directly on the control PC, after the uncovering of the plastic shell. Then we will start the Internet Explorer Application. In case it is permissed the automatical set up of the protocol TCP/IP it is not necessary to set up it manually. Or if it is not pre-set up, we have to do this manually. We open the offer of the wire setting:Start, My Network Places and in the left column we click on the line View network connection. We click on the pictogram Local Area Connection 2 and in other window we click on the button Properties. In the protocol schedule we choose the Internet Protocol /TCP/IP) and we will press the button Properties.Then we set up the network parametres.

G. The connection to the remote control by the help of program TEAM VIEWER and Internet

In case we need the SW technical support and we have to make accessible all SW of the control PC, we use the special program TEAM VIEWER. Withal has to be connected the cabel into the appropriate connector LAN of the control PC.

First we contact the technical advicer by the phone and after start of the progamme TEAM VIEWER we tell him of nine-digits number (ID), with which was the program TEAM VIEWER started. After this can the technical advicer enter to the control pc and provide some essential operations.

H. Keybord option

The external keybord can work in the international mode QWERTY, or in the mode of czech keybord QWERTZ.

I. Restart or switch off of the PC

This we will do ordinarily – RESTART or SHUT DOWN. When we shut down the PC it is important to finish the OS WINDOWS EMBEDDED and then switch off the PC.

4.2.10 The ending of control SW

To this purpose we will push the button EXIT on the display of the basic menu.

4.3 Preparing the Device and the Patient for Procedure Administration

Testing and verifying possibilities to control the process of vacuum-compression therapy can be carried out with a blind neck of the application cylinder (1), using an appropriate seal/cover, which is usually supplied with the device. Then, you can proceed with the administration of vacuum-compression therapy procedures to a proband or patient (in accordance with the relevant indications and contraindications).

The device is turned off, travelling wheels (14) are secured with brakes in applied positions. The closing circular rings (19) at the external part of the neck (8) of the application cylinder (1) are to be gripped at the point of diagonally placed metal pegs, turned with them so that three circular cut outs along its periphery are precisely above the circular heads of securing bolts fixed in the Plexiglas ring completing the neck (8). Then, remove the closing circular rings (19). Remove the insertion piece of cuff pressurization (20) and unscrew the securing nut of the cuff orifice. Then, you can easily remove both the sealing cuff (9) and internal supporting intermediate ring (18) from the cylinder neck (8).

Normally, clothing from the patient's treated extremity is to be removed as a clothing layer may prevent proper sealing the extremity in the cylinder neck. At the same time, the presence of clothing on the extremity precludes an important diagnostic possibility of observing colour changes in the extremity during the procedure. Clothing from certain types of fabric, however, may not prevent from sealing the extremity (for example, denim of „stretch" type). In the positive pressure stage, the extremity should get pale; in the negative pressure stage, the extremity should get red as a result of fresh blood supply. These colour changes, however, may have be demonstrated in a very inconspicuous manner, and they may appear after running more cycles of the procedure, or even after administration of a number of procedures. So, if during vacuum-compression therapy, therapeutic effects are achieved also without visible expression of colour changes of the extremity, the absence of these colour changes is not the cause for termination of therapy. In majority of treated patients, changes in colour are apparent. In the negative pressure stage, these changes would be observed in the most distal part of the extremity (for example, on a plantar side of the great toe). Permanent absence of colour changes may be caused by improperly selected parameters of procedure (such as the low value of negative pressure or - more frequently - short duration of this negative pressure). However, if, in spite of changes in parameters of procedure, you consistently observe that redness in the extremity in the negative pressure stage reaches in the distal direction only a certain level, and it does not continue behind it, this may be a manifestation of a demarcation zone separating the distal part of the extremity, where a serious organic serious blood disorder exists, and this should be carefully diagnosed and resolved.

Any bandages, covering, for example, chronic skin ulcerations (varicose ulcers), are mostly not removed during the VCT procedure. In this manner, significant contamination of the application cylinder is prevented. Bandages are to be removed only if this can have a diagnostic importance (for example, objective assessment of possible bleeding from a wound, or a defect on the extremity during the procedure).

The patient's extremity prepared for treatment is in front of the orifice to the neck (8) of the application cylinder (1). To meet this condition, the brakes of travelling wheels can be released, desired position of the Extremiter found, and the brakes of travelling wheels applied. Then, using the remote control (11), you can adjust the approximate height of the application cylinder (1) and its slope.

Caution: In doing so, keep the remote control as close as possible to the plastic cover of the device base in the area under the control computer (12). This requirement must be respected, especially in a strong electromagnetically interfered environment. The remote control signal itself can not be too strong to avoid interference of other high-frequency electromagnetic sensitive equipment in the vicinity of the device.

Estimate, which inner diameter of the internal sealing cuff (9) corresponds to a thickness of the treated extremity. Verify the accuracy of the cuff by preliminary putting the sealing scuff (9) on the extremity. At the point of sealing the extremity, the cuff should enclose the extremity closely, but still slightly. The internal cylindrical surface of the cuff (9) can be treated with cosmetic glycerine. This will increase the life of the cuff, and facilitate its putting, especially on a haired extremity. Please not that the glycerine,

however, can get dry after a certain period of time. At certain leakages between the cuff and extremity at the point of its required sealing, you can also make use of simple or coaxially compound neoprene rings. The sealing cuff, or neoprene circular rings, as well as all internal space of the application cylinder (1) must be properly cleaned and disinfected. If it is necessary to ensure a high level of hygienic separation of the treated extremity from the internal environment of the application cylinder (1) and from the sealing cuff (9), a long narrow protective bag can be put on the extremity first, which covers the whole extremity and overlaps from the neck of the cylinder. For this purpose, narrow micropore bags are usually used, but they can not be considered as means of sterile separation, but only as hygienic aids. Special silicone sterile sleeves are purchased only in the event of specific requirements. Practically, any cover on the extremity prevents the diagnostically significant observance of colour changes in the extremity during the procedure.

According to the internal diameter of sealing cuff, select the appropriate supporting (18) and closing (19) circular rings. The internal diameter of circular rings should be 1 – 3 cm larger that the internal diameter of sealing cuff (9). The extremity should never come in contact with supporting or closing circular rings.

Caution: To quickly select sealing cuffs, or supporting and closing circular rings, you can advantageously use a wall-mounted suspension magazine.

First, insert the supporting circular rings (18) into the neck (8) of the application cylinder (1). Then, insert the sealing cuff (9). Make sure the correct orientation of its orifice so that it precisely comes through the opening at the top part of the cylinder neck (8). Press the sealing cuff (9) upwards at the point of orifice. In doing so, support the orifice with hands through the opening in the neck (8). Then, screw up the securing nut to external threading of the cuff orifice (9). Complete the sealing assembly of the cylinder neck (8) by adding selected closing circular rings (19). Put the cut out segments over the circular heads of securing bolts fixed to Plexiglas ring finishing the neck (8). Pin down the closing circular rings uniquely and sufficiently in the direction of cylinder neck, and turn the circular rings up to a stop element. In this manner, you prepared the sealing assembly of the cylinder neck. Finally, do not forget to insert firmly and press the insertion piece of cuff pressurisation (20) into the orifice of the fixed sealing cuff.

Caution: The cylinder neck assembly is more practically implemented if the application cylinder (1) is in a slight elevation, it means that its neck (8) is in a slightly upward position. In this position of the cylinder (1), the inserted elements of the cylinder assembly do not slide out of the neck.

Now, insert the patient's extremity to the cylinder neck (8) and put the application cylinder (1) on the patient's extremity by travel of the supporting arch (2), or superposed travel of linear guide (4).

Caution: Do not forget to apply the brake (by the remote controlled electromagnetic brake) on the travel of supporting arch (4) – position BRAKE OFF, as well as secure the locking handle (5) of linear guide (4). Also check that the brakes of travelling wheels of the entire device are applied.

Note: If in some cases, it is better to travel with the entire device to the patient and insert the treated extremity into the application cylinder (1) in this manner, it can also be used without problems. First, release the brakes of all 4 travel wheels (14), lift up the patient's extremity in the direction of cylinder neck orifice (8), travel back with the entire device, first in the direction from the patient's extremity, then towards the extremity. Movement with the entire device before putting the extremity into the cylinder neck should be performed along an adequately big circle or ellipse, whereby the travelling wheels, freely rotating along their vertical pins, will be set up to the correct travel direction at subsequent travel with the entire device on the extremity.

In putting the extremity into the application cylinder, it is practicable that the extremity slides easily along the internal cylindrical area of the applicator (1), especially if the patient cannot lift up its extremity. This can be achieved in different ways: For example, remove a pad (to pad out the extremity) from the application cylinder (1), insert a hygienic medical grade paper or similar material under the distal part of the extremity (most frequently under the heel or under the arm), so the extremity can be slightly slid down when the application cylinder (1) moves. In more complicated cases, you can open and remove the cylinder bottom (27) and manually handle the extremity in the cylinder. In the removed bottom of the application cylinder (27), the extremity can be optimally padded

out. Padding of extremity is very important in order to prevent any callous (heel, arm), as well as to ensure the optimum slope of extremity directly in the application cylinder. The treated extremity should be positioned in the axis of the application cylinder. This is an important condition. This condition is usually well met for the lower extremity due to its suitable anatomy. The upper extremity, however, especially if slim – directs mostly through the cylinder neck sidelong downwards – out of axis of the application cylinder (1). In this manner, the sealing cuff is unnecessarily pressed in the cylinder neck (8) under the extremity, and there is created an opening above the extremity, and automatics of the device cannot easily seal this opening. Under this situation, only partial success can be achieved by tilting the application cylinder (1) using the remote control (11). In these cases, it is necessary to pad out a distal part of extremity (usually hand and forearm) after its insertion into the cylinder (1). For this purpose, partially inflated exercise balls of suitable sizes are very convenient. Distal part of the extremity „sinks" into these balls, and the extremity is well positioned in the application cylinder. This procedure mostly does not put increased requirements for the operating personnel, because a partially inflated smaller ball can be inserted into the application cylinder (1) before insertion of the treated extremity and the patient (if he/she can move with the extremity) will put the extremity on this small ball by himself/herself. If the patient's ability to move the extremity is considerably limited, it is necessary to open the cylinder bottom (27) and pad out the extremity. Various diagnostic sensors of biological quantities, and the like, are also inserted through this opened bottom (27) of the application cylinder (1) and put on the extremity.

If higher values of positive pressure are used, it is suitable to connect the patient's chair and device with a fixation belt. In application of usual values of positive pressure, the brakes of device wheels (14) should be thoroughly applied.

At the end of patient's preparation for application of VCT procedure, adjust slightly the position of the application cylinder by its minor lifting up (UP) or down (DOWN), or tilting. These actions are performed using the remote control (11). In doing so, you usually should stay at the neck of the application cylinder (1) and check whether the extremity is enlaced (surrounded) with the sealing cuff (9) along the sealing periphery fully uniformly, i.e. the extremity should not press excessively the cuff at any place. In this case, the extremity is not sealed optimally during the procedure.

4.4 Administration of Vacuum-Compression Therapy Procedure

Administration of vacuum-compression therapy procedure is performed by means of control computer (12) with touch screen (13) in the manner described in detail in Chapter 4.2. The vacuum-compression therapy procedures can be administered only according to regulations or recommendations of a physician, regardless of pre-programmed procedures and know patient's diagnosis.

The patient should be under the permanent, at least remote, supervision of a qualified medical operating personnel of the device.

4.5 Completion of Vacuum-Compression Therapy Procedure

The procedure will be automatically terminated after the elapse of a pre-selected procedure time, or after the elapse of a pre-set number of cycles (periods). Then, the procedure can be repeated with the same biotropic parameters, or other procedure can be selected, or the control software can be stopped.

Note: After finishing the procedure and removal of the extremity from the application cylinder (1), the cylinder can be ventilated, it means air flow can be used and mist or odour can be removed.

In the event that it is necessary to terminate prematurely administration of procedure during the procedure, it is necessary to choose a method of premature termination, corresponding to urgency of arisen situation. If possible, wait until the negative pressure in the application cylinder is reduced. At the time when the zero (atmospheric) pressure is reached in the cylinder (1), end the procedure by pressing the **STOP** button. However, if the situation is extremely urgent, you can end the procedure at any time. The extreme possibility how to end the procedure is to remove the insertion piece of

pressurisation (20) from the orifice of the sealing cuff (9). In most cases, this operation can also be made by the instructed patient. In other cases, permanent surveillance must be present at the patient.

After ending the procedure, the operator of this device will remove the insertion piece of pressurisation (20) from the orifice of the sealing cuff (9). This will release any residual pressure from the cuff. Then, do not let the patient himself/herself to "slip out" of the application cylinder (1), but, using the remote control and electromagnetic brake, release the travel of supporting arch (4) and application cylinder (1) from the patient's extremity. If the movement of app. 30 cm was not sufficient, release the locking handle (5) of linear travel (4) and continue in shifting away the application cylinder (1). If so requested by situation, open and take away the cylinder bottom (27), and handle the extremity from this side. Finally, take out the treated extremity through the neck (8) of the application cylinder and leave the patient to relax for a certain amount of time. Then, continue with treatment of the other patient's extremity, or treatment of other patient. However, you must clean and disinfect internal areas of the application cylinder (1) first, sealing cuff (9), or other parts of the device, which may come into contact with the patient's body. It is the responsibility of a physician or a qualified and responsible health professional to decide about disinfecting requirements.

Note: The application cylinder (1) can be removed from the patient's extremity also by travelling with the patient's armchair in the back direction, or movement of the entire device in the forward direction (the wheel brakes must be released).

Note: In drawing the extremity out of the sealing cuff (9), it is necessary to take care and do not deform or damage the cuff. The cuff can excessively adhere to the extremity during the procedure. Therefore, before the procedure, it is advisable to treat the contact cylindrical surface of the cuff (9) with the extremity with a suitable agent – for example, cosmetic glycerine. In the course of loading and removal of extremity, the cuff must always be released from the extremity.

4.6 Operation of the Device in a technical – Service, Calibration, and Control Mode:

The device EXTREMITER 2010, „BETTER FUTURE" manufacturing edition, includes very advanced technical – service, calibration and control modes, realised by modern automated hardware and software technologies. Any intervention with these modes can be performed only by the qualified expert who was demonstrably trained and authorised by the manufacturer of this device, and equipped with necessary technical means. Any unqualified interference with these modes leads to the risk of damage to the device and a potential danger to the patient.

For the device EXTREMITER 2010, „BETTER FUTURE" manufacturing edition, one-year regulatory time period is prescribed to perform protocolar checks of trouble free functionality, recalibration, and full safety of this medical device.

The computer memory also contains all given procedures and their parameters, as well as related reports of the control unit, throughout the life of the device (if such data are not deleted purposely).

In the case of a qualifying requirement, and in compliance with the relevant legal provisions, remote entry to the control computer may be performed via the internet. This option can be used for remote technical service, as well as for the purposes of a promising telemedical approach in physical therapy and diagnostics.

4.7 Cleaning and Disinfection

The entire device assembly should be kept clean and effectively prevented its excessive pollution of contamination.

If the device is not used for a longer period of time, cover it or pack into a protective foil. Under normal operation, dust should be regularly wiped, suctioned, or removed, using soft and dry means. If considerable impurities need to be removed, use a soft gauze, cloth, or sponge slightly humidified with water, or a friendly cleaning agent. Never use alcohol-based cleaning agents, or abrasive means. For

polishing, or renewal of Plexiglas of the application cylinder, the manufacturer of PLEXIGLAS GS recommends special means.

Important note:

Alcohol-based cleaning agents, or abrasive means must never be used for cleaning of the device or its parts.

Applied parts of this device, the application cylinder (1), manufactured from annealed Plexiglas, PMMA, and sealing cuff (9) manufactured from medically safe rubber (resp. auxiliary neoprene rings) can get in contact with the patient's body. Therefore, it is necessary to keep clean all these parts of the device, and to rule out the situation when these parts would become a source of any pathogens.

During the procedure, clothing must usually be removed from the extremity. However, as we mentioned previously, any bandages covering, for example, chronic skin ulcerations (varicose ulcers), are not to be removed during the VCT procedure in majority of cases. In this manner, significant contamination of the application cylinder is prevented, and administration of procedure is simplified. The therapeutic effect will not be influenced in any way. Bandages are to be removed only if this can have a diagnostic importance (for example, objective assessment of possible bleeding from a wound, or a defect on the extremity during the procedure). The treated extremity can also be protected with a suitable protective coating. If this coating is made from a micropore bag, its role is only hygienically supportive. Sterile sleeves (usually from silicone) are used only exceptionally.

If, despite all the protective measures, there is a contamination of attached (or other) part of the device, and/or, it is necessary to disinfect the device before its using at the next patient, disinfection of any part of the device can be made by the use of common disinfectants according to the Disinfection rules of a particular medical facility and/or decision of a responsible physician (medical professional), but only:

- by alcohol free means,
- by means which do not leave colour traces or discolouration or damage of surfaces of the device,
- by friendly application of disinfecting means.

It is always necessary to follow the recommendations and instructions of manufacturers of disinfecting agents.

The removed application cylinder (1) can also be sterilized.

Important notes:

During cleaning and disinfection of the device:

- *the device must be switched off by withdrawal of the mains plug from the mains socket,*
- *must be ensured that any liquids or particles will not ingress into the inside of closed, encapsulated parts of the device.*

CAUTION:

The applied part of the device, in particular, the application cylinder (1) and sealing cuff (9), is not intended for contact with a non-intact damaged or problematic and hypersensitive skin.

Note:

By special customer's request, the application cylinder of the device can be equipped with other means increasing cleanness and comfort for administration of VCT procedures:

The inlet of pressurization section of the application cylinder (1 – see the insertion piece of pressurization (21a), can be provided with
a small vessel containing the HEPA (High Efficiency Particulate Air) filter, which ensures filtration of air entering the application cylinder (1), and, at the same time, excess water vapours from the pressurization circle can condensate in this vessel, whereas the water condensate can be released from the vessel after releasing a particular valve in the bottom of the vessel. The valve must be closed again after this action. The vessel can also be screwed out, cleaned up, and dried up. A particular filter can also be replaced at the removed vessel.

In addition to the above described filtration and condensation vessel, another vessel can be integrated, filled with a suitable solution whose vapours do not damage materials from which the application cylinder is made (Plexiglas), as well as other HVAC elements (stainless, polyethylene, polyurethane, and the like).
Vapours of this solution should have auxiliary disinfection effects, and they act as nice fragrance agents. During pressurization of the application cylinder, this solution is suctioned on the principle of airbrush, and ultra fine drops of solution fill with very fine aerosol particles the area of the application cylinder and entire pneumatic circle of the device, and, subsequently (after opening the cylinder) also environment of the patient's device.

Another filtration and condensation vessel can be placed at the vacuum exit from the application cylinder (1) – see the insertion piece of vacuum application (21b). A relevant filter in this vessel ensures a certain rate of filtration of air leaving the application cylinder (1) during the procedure.

Air suction and air exhaust into the atmosphere is always provided with standard filters inside the device. While any external additional filters located at the bottom (10) of the application cylinder (1) are cleaned and maintained by the operator of the device, filters hidden inside the device are replaced during regular checks of functionality and safety of device within the framework of its technical maintenance, and these activities are performed by the qualified, trained, and by manufacturer authorised technical personnel.

4.8 Maintenance

Routine maintenance performed by the operating personnel consists only in a regular and on-going integrity check of those parts of the device that effect its safety as described in this manual; as well as maintaining the device in cleanness and in a necessary disinfection condition. The operating personnel must observe all safety instructions specified in this manual or provided during installation of the device and/or training of operating personnel. In addition, it is also necessary to observe the instructions specified in this manual or any apprehensible changes in appearance and function of the device or its individual parts. If any discrepancies are found, the authorised service should be contacted.

The additional device type CO2 Therapy edition „Better Future" is except the germicidal lamp equipped by two HEPA filters, their exchange is necessary during the device running. These corpuscular filters with high effectivity minimally 99,99% catch the firm and the liquid elements including viruses, bacteries and germs of sporidiosis, also many air toxins and radioactive elements. The producer of these filters requires their exchange after each device running, but the time of the running is not specified. The primary using of mentioned filters is in the medical-area detach epecially for the protection of the medical stuff against consequential infections type SARS etc. at using these respiratory filters in appropriate masks or half-masks.
The intervals for the filter-exchange is necessary to set directly at running of the device. It depends on the dustiness of the environment, potencial concentration of the infectious germs in the air of the working place and naturally above all on the state of the treated extremities, on the presence of their surface microbial flora and on the exposure for the pacients and for the stuff. The interval of the filter exchange is suitable to take into the disinfection rule of the appropriate medical working place. The service life of the original packaged and appropriate stored filter (-10 C till + 50C, 75% Rhmax.) is 10 years. After the removal from the original packing is the lifetime of the filter 6 months (what is the longest possible time its persistence in the device). The demands for the surrounding are 0 C till +40 C, Rhmax. 95%.

Before the filter exchange switch off the device.

The exchange of the first filter (see the picture no.7 – the one with the white cover) is made by screwing of the old filter in the direction to the left and by screwed the new filter in the direction to the right. The exchange of the second filter (see the picture no.7 – the one with the black cover) will be made by the same way after the uncover of the cylinder´s cap.

Use only the prescripted filters by the producer: 2 pcs, the type PF10 P3/PSL, code 052670.
Very effective HEPA filter. It responds to the class P3.

Caution: In case of the filter´s exchange till 15 minutes from the shutoff of the device, could be silvery rustless cylinder of the cover of the germicidal lamp hot and it can threaten the possibility of scorch of the stuff.

4.9 Regular Functional and Safety Checks of the Device

The device EXTREMITER 2010, „BETTER FUTURE“ edition, is a medical device whose safety and functionality can be assessed only by the manufacturer, or by qualified and adequately equipped person authorised by the manufacturer. According to the local legal provisions and regulations in force, it is the responsibility of relevant institution who utilises the device to ensure its regular inspections, i.e. regular checks of functionality and safety.

The manufacturer recommends performing these checks once per year. A check report must be prepared about the check performed, and the responsible institution (health facility, physician, physiotherapeutist, and the like) meets in this way the requirements of EU legislation regarding medical devices.

In the course of periodic inspection – regular functional and safety checks, the authorised service performs prescribed maintenance actions of electric medical devices, as well as measurement of positive pressures and other decisive physical quantities. In doing so, the device is to be recalibrated on a regular basis. If parts of the device exposed to pressure are regarded „pressure vessels“ according to local regulations in force, it must be carried out their inspection and measurement; consumables must be replaced and completed, and worn operational components must be replaced. In any problems are found, necessary repair work must be performed. The user of this device is informed about all new facts ascertained, regarding the operation of this device.

4.10 Environmental Protection and Disposal of the Device

The device EXTREMITER 2010, „BETTER FUTURE“ edition, does not have any direct negative impact on the living environment. From the viewpoint of applied pressures, it is only necessary to ensure protection from their undesirable effects (max. 25 kPa in the volume of appr. 70 litres). The device under operation has a small power take-off (max. 220 VA).

After the elapse of its life time and putting the device out of operation, it must not be disposed of as municipal waste, but it must be dismounted to individual components as outlined below:

metal parts (structural steel, stainless steel, non-ferrous metals),
plastic parts (Plexiglas, fibreglass, polyethylene hose, neoprene rings, and the like),
rubber parts (sealing cuffs),
printed circuit boards with electronic components,
electromechanical parts and electric equipment (such as motors and compressors),
personal computer,
cabling, and the like.

Waste materials are disposed according to their nature and in accordance with local regulations and statutory regulations in force and in necessary cooperation with specialized accredited companies dealing with waste disposal.

No dangerous waste is included in the device. The device does not produce any waste products that would have the excessive environmental impact.

On disposal of the device, contamination of device parts from bodies of treated patients should be considered.

Important notice:

With regards to its natural wear and tear, material ageing, and, in particular, moral ageing to which all electronic devices are exposed, the life time of the device is 10 years.

For this period of time, service and possible deliveries of spare parts are ensured.

4.11 Packaging

For the purposed of transport, at least the application cylinder (1) and any freely movable and smaller parts should be separated from the device assembly. Then, these parts are to be packaged into protective packing foils. In this manner packaged device can be transported only by the manufacturer. For common transport, individual parts of the device are placed into a wooden transport case, fixed with fixation boards and bands. In addition, the transport case must contain the Accompanying User's Documentation (User's Manual). The transport case must be properly marked.

4.12 The operation conditions and storage

The following storage conditions are to be applied:

Temperature	Working: 0 till +40 C Storage: -10 till +50 C
Relative humidity	Working: 15 till 95% Storage: 5 till 99%
Atmospheric pressure	Working: 425 till 809 mmHg Storage: 120 till 809 mmHg

4.13 Transport

Transport cases with devices can be transported by common covered means of transportation without heavy shocks. The device packaged in a transport case must be handled with care, similarly as with fragile shipment; side up, do not exceed the permissible storage conditions.

4.14 Parts of the device and expendable supplies

The basic device with the removable app.cylinder

The control computer with the sheating

Application position chair

Sealing cuffs from the natural rubber (standard 6 pcs)

Screwed outlet of the sealing cuff valve

Neoplene inlays (standard 12 pcs)

Sealing stainless annulus (standard 4 pcs)

Supporting plastic PMMA annulus (standard 4 pcs)

Fixation belt (for fixation of the pacient to the appl.cylinder, only by higher overpressure)

Bed rest to the application cylinder

Overball into the app.cylinder

Remote control

Line connector

UPS power supply

The stanf for material (sealing cuffs etc.)

5 The additional arrangements to the device Extremiter 2010 “Better Future” edition

5.1 CO2 Therapy “Better Future”

The simultaneous application of carbon dioxide along with the ongoing therapeutic procedure of vacuum-compression therapy is a very useful combination of physical and therapeutical biochemical effects. To achieve these therapeutic effects, the Extremiter should be complemented with a special electonically controlled mixing and filtration equipment and necessary technology for the distribution of

medical gases, as well as appropriate technology for effective disinfection of gaseous medicine media and CO2 recycling. This solution ensures the medically desired concentration of CO2 in the applicationcylinder of the Extremiter device, and extremely low gas consumption, while maintaining high safety standards of patients and operators.

5.2 Pacient´s monitoring

Patients diagnostics monitoring in real time and during the procedure enables treatment results objectivisation as well as feedback impedance controll of the procedure which is important for maximal treatment effects. (For extremity volume changes monitoring, for vascularisation and arterial blood oxygen saturation monitoring).

5.3 PC Supervision

It is a supervising PC laptop with monitoring and control SW. The supervising PC is an instrument for a doctor or head physical therapist on his/her workplace (remotely from the device) allowing, procedure prescription for a particular patient, sending the prescription electronically directly to the control computer of the device.